

# MEDICAL PLASTICS DATA SERVICE

A TECHNO-ECONOMIC NEWS MAGAZINE FOR MEDICAL PLASTICS, MEDICAL DEVICES, DIAGNOSTICS AND PHARMA INDUSTRY

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## • Plastics For Cardiovascular Devices

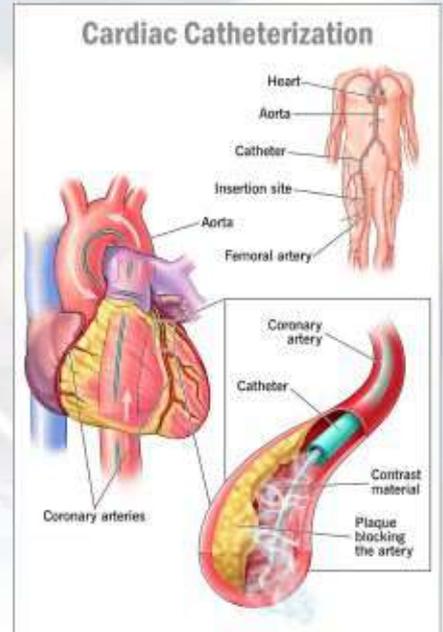
- Cardiovascular Diseases
- Cardiovascular System & Structure
- Cardiovascular Device Applications & Markets
- Polymeric Materials / Plastics Used
- Classifications of Polymers Used
- Regulatory Perspective
- New Technologies & Innovations
- Catheter Tubes For Cardiovascular Devices



- Shape Memory Polymers For Medical Applications
- Chemical Characterization Of Medical Devices
- Medical Device Supply Chain & Contract Manufacturing - Regulatory Issues
- Optimal Hospital Plastics Recycling
- Mexico Medical Devices Market



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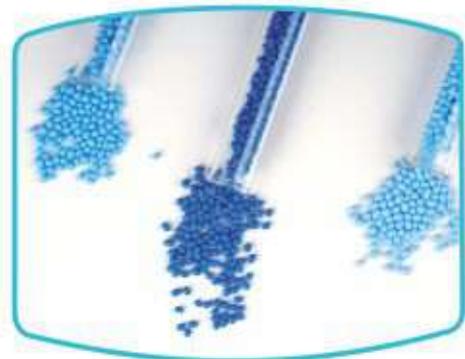
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Sai-45P	45 MM	26:1	15 HP AC	2mm-10mm	L-11M X W-2M X H-3M
Sai-50P	50 MM	26:1	20 HP AC	2mm-12mm	L-12M X W-2M X H-3M
Sai-65P	65 MM	28:1	30 HP AC	3mm-20mm	L-14M X W-2M X H-3.5M
Sai-80P	80 MM	28:1	60 HP AC	5mm-40mm	L-16M X W-2.5M X H-3.8M
Secondary Extruder	Available For Lining, 20mm/25mm/30mm on Demand				

## Our Product Range



**IV Canula Medical Tubing Extrusion Line**



**Winder**



**Caterpillar**

Model	Extruder Size	L/D Ratio	Main Motor	Product Size	Space Required
Sai-20/16C	20/16	28:1	3K.W/2.5K.W	14-26 Gauge	L-9.5M X W-2M X H-2.25M
Sai-25/20C	25/20	28:1	3.5K.W/3K.W	14-26 Gauge	L-10.5M X W-2M X H-2.5M

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**Sai Extrumech Pvt Ltd**  
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☎ Mr. Rajbir Singh (Senior Vice President)  
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Mr. Vivek Mehta (Managing Director)  
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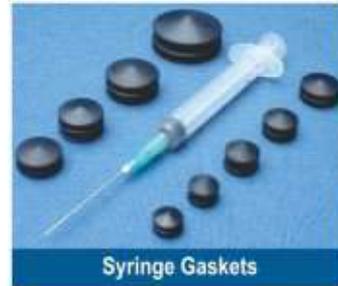
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- Ambu Bag - Adult / Paed / Neo
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- Bain Circuit - Adult / Paed
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- B-pap Mask & C-pap Mask All Type

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- 3-Way Extension Line
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- Dial Flow Regulator
- I. V. Set With Flow Regulator
- Codan Set

#### MISCELLANEOUS

- Nebulizer Compressor Machine
- ECG Paper & ECG Accessories
- Patient ID Belt
- Oxygen Flow Meter
- Cautery Pencil

#### UROLOGY & NEPHROLOGY

- Urine Bag - All Type
- Urine Bag With Urometer
- Hemodialysis Catheter Kit
- Neltan Catheter
- Blood Tubing Set
- AV Fistula Needle
- DJ Stent - All Type

#### GASTROENTROLOGY

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- Infant Feeding Tube
- Ryles Tube
- Stomach Tube
- Kher T Tube
- Levins Tube
- Selum Sump Tube

#### SURGERY & DRAINAGE

- Suction Catheter
- Thoracic Drainage Catheter
- Abdominal Drainage Kit
- Close Wound Suction Set
- Yankaur Suction Set
- Umbilical Cord Clamp

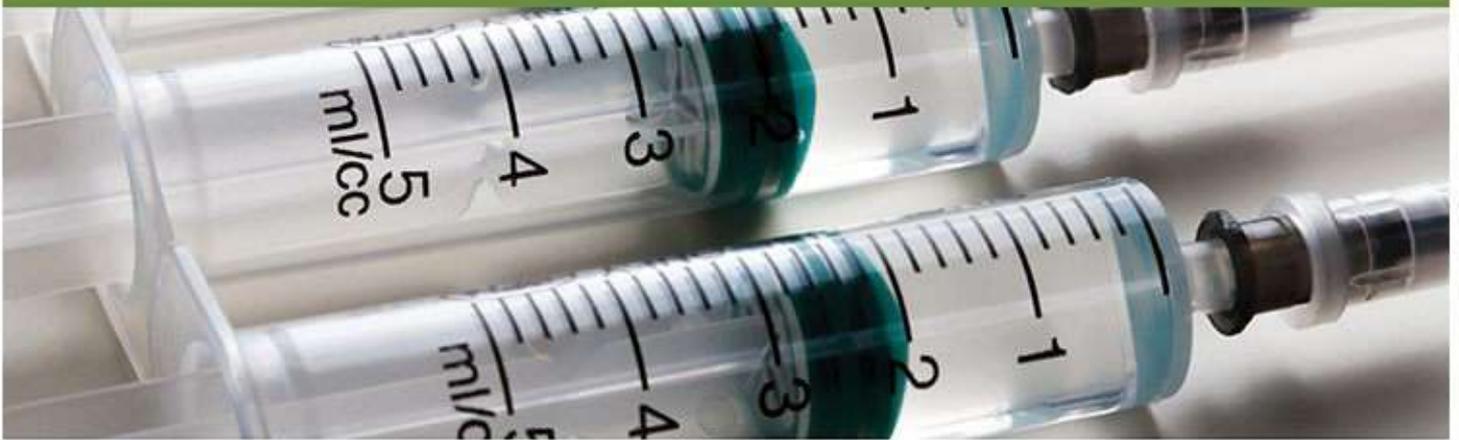


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1. Biocompatibility Testing of Medical Devices (As per ISO 10993-1:2018)

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- Skin Sensitization Testing (ISO 10993-10)
- Irritation or Intracutaneous Reactivity Test (ISO 10993-23)
- Acute Systemic Toxicity Test (ISO 10093-11)
- Material Mediated Pyrogen Test (ISO 10093-11)
- Sub-Acute Systemic Toxicity Test (ISO 10993-11) Sub-Chronic Toxicity Test (ISO 10993-11)
- Chronic Toxicity Test (ISO 10993-11)
- Implantation Test (IM/SC/ Intraocular/ Intra-biliary / Intra-arterial) (ISO 10993-6)
- Genotoxicity Tests (AMES, CHA, MNT) (ISO 10993-3 & ISO 10993-33)
- Hemocompatibility Tests (ISO 10993-4)
- Carcinogenicity Test (ISO 10993-11)
- Reproductive / Developmental Toxicology (ISO 10993-11)
- Degradation Testing (ISO 10993-9, ISO 10993-13, ISO 10993-14 & ISO 10993-15) Toxicokinetic study of Degradation Products (ISO 10993-16)
- In-vitro Skin Irritation Test (ISO 10993-23)
- In-vitro Skin Sensitization Test (ISO 10993-10)
- Mucosal Membrane Irritation Test (Oral, Ocular, Penile, Vaginal & Rectal) (ISO 10993-11)
- Biological Evaluation Plan (BEP) & BER
- Toxicological Risk Assessment



2. Chemical Characterization /Extractable & Leachable Testing of Raw Material & Finished Medical Devices



3. Biological Testing of Raw Material of Plastics, Rubber, Silicon, Polymers, etc.



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The Pioneer of Medical Devices Development in India





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- Evaluating Microbial Barrier Qualities
- Thermoforming Automation
- PLA : For Healthcare Packaging



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**Technology**

- Nano composite Dental Materials
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**Medical Plastics Global Markets**

Venezuela

- Recent Advances
- Safe & Effective Production
- Circular Economy



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**Medical Devices Sterilization**

- Microbiological Contaminants
- Sterility Assurance Levels Prescribed
- Sterilization Methods
- Ethylene Oxide Alternatives For Sterilization
- Process Validation & Other Challenges



**Medical Polymers & Devices**

- The Future of Medical Device Design
- 3D Innovations : How Medical Polymers Revolutionize Pain Management in Medical Practices
- PVC Medical Devices : Emerging Trends
- Importance of Precise Placement of Double-Lumen Tube during Anaesthesia & Surgery

**Technology**

- Facilities/Center For Industrial Plastic Technologies
- Plasma Technologies For Purification and Sterilization
- Plasma Pyrolysis Technology for Disposal of Biomedical Waste
- Plasma Jet : Sterilization Applications



**Medical Device Manufacturing**

- Medical Device Manufacturing: Importance of Supply Chain
- Medical Device Sterilization
- ILS FDA :
  - Harmonization & Modernization of Regulations
  - Disposal in Springs : Quality Failures



**Materials**

- PVC Vs. Other Polymers in Medical Device
- EU Report On Essential Role of PVC in Healthcare
- Adhesives For Medical Device Applications

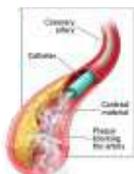
**Peru Medical Devices Market**

**Dr. Binay Bhattacharya**  
Managing Director, AMTZ (P), Bangalore  
Key Regulators/Experts of Contract Manufacturers

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# Table of Contents

Vol. 32 No. 5 Sept.-October 2024



23

## COVER STORY

### Medical Plastic Catheter Tubes for Cardiovascular Applications

Cardiac catheterization is a common method to diagnose or treat a variety of heart problems. A catheter is a thin tube made of medical-grade materials used for various medical purposes.



27

### Plastics in Cardiovascular Medical Devices

**Dr Ajay D Padsalgikar**, pH.D., Technical Director, Biolinq Inc. USA

The article is focused on the cardiovascular sector explaining the cardiovascular system, the typical devices used in the cardiovascular area and the role of plastics within them. It highlights the type of plastics traditionally found usage in this sector as well as the cardiovascular medical devices market.



29

### Polymers for Cardiovascular Applications.

**Dr Renjith S. and Dr Gijo Raj**, Biomedical Technology Wing, SCTIMST, Trivandrum

The article introduces various Cardiovascular applications, gives a detailed information on the synthetic polymers used in such applications with a special reference to "TTK-Chitra Heart Valve" as well as other Cardiovascular Devices developed by the "SCIMST".



33

### Cardiovascular Devices – A regulatory Perspective

**Ms Rajashri Survase-Ojha**, Founder & Director, Raaj GPRAC Pvt Ltd, Mumbai

In a free-wheeling interview, Ms Rajashri Survane-Ojha gives regulatory perspective on Cardiovascular Devices including regulatory concerns. She has also explained how medical device industry professionals can support the growth of the industry in India.



37

## MATERIALS

### 100 Benefits of Plastics in Medical Devices SPE INDIA MEDICAL PLASTICS DIVISION

In light of the negative attention surrounding the term "plastics" it is crucial to remind ourselves of the multitude of benefits plastics offer. To reaffirm this, SPE INDIA MEDICAL PLASTICS DIVISION has compiled a comprehensive list of 100 benefits of utilizing plastics in medical devices.



39

## INNOVATIONS

### New Technology and Next Gen Vascular Interventional Medical Devices

**Ravi Shankar Srivastava**, Managing Director, Conquest Medtech LLP, Mumbai

The article highlights "New Technology and Next Gen Design Vascular Interventional Medical Devices" including Bio absorbable Stent, Drug Eluting / Drug Deliver Balloon, Heart Valves and more



41

## QUALITY

### Introduction To Chemical Characterization of Medical Devices

**Dr. M R Murali, Dr. S S Murugan, Dr. T S Kumaravel** - GLR Laboratories Pvt. Ltd.

Chemical characterization is a critical step in the biological evaluation of medical devices. This process is essential for assessing potential biological risks and ensuring patient safety. This characterization helps to understand the material composition and predict potential biological effects, forming the basis for further biological testing and risk assessment.

# Table of Contents

Vol. 32 No. 5 Sept.-October 2024



41

## MANUFACTURING

### Regulatory Issues In Supply Chain & Contract Manufacturing (Out Sourcing) Of Medical Devices

**Sanjay Shah**, Founder, Unikal Consultants

Suppliers in the Medical Device industry, should have a good understanding of needs and requirements including need to understand their role as per MDR & maintain their Quality management System. They also have to have their share of responsibilities.

43

## GLOBAL MARKET : MEDICAL DEVICES

### Mexico Medical Devices Market

**Mr. Amit Dave** - M. Pharm, MBA, Former CEO – Brazil operations/ Vice President Export - Zydus Cadila Claris Lifesciences

**Mexico Highlights :** Very large market for medical devices, Regulatory framework simple but unexpected delays likely, huge import of medical devices, competition from US companies.

45

## AI MeD & REGULATORY UPDATES

- Exclude Medical Devices From The List Of India-EU Free Trade Agreement (FTA) Items: AiMeD
- Govt Considers Random Testing Of Imported Medical Devices
- India To Offer 20 Per Cent Capital Subsidy For Domestic Production Of Medtech Components

47

## INDUSTRY NEWS

- Make In India' In Focus, AIIMS To Set Up Centre For Medical Devices With Osaka University
- Andhra Pradesh MedTech Zone ( AMTZ ) Launches India's First Indigenously Developed Mpx RT-PCR Kit
- Kerala's Advances In Biomedical Device Development Sector In Spotlight At BioConnect 2.0

49

## PRODUCT GALLERY

Bry-Air Enhances Medical Plastics: The Right Choice for Resin Drying

21

## DID YOU KNOW?

### About Shape Memory Polymers (SMPs) for Medical Applications

These polymers (like shape-memory alloys) will “remember” their original shape when deformed, and flip back to the initial shape when exposed to an external stimulus. The medical devices based on SMP can be implanted into body through minimally invasive surgery in contraction or folded state and recovered to their requisite original shapes at target position.

40

## FAST FACTS

- Ethylene oxide is the most commonly used method to sterilize medical devices manufacturers and contract sterilizers worldwide.

48

- How COVID-19 changed medical device clinical trials forever

# Flashback

## MEDICAL PLASTICS DATA SERVICE

### Select Article Index

July 2021 to January 2022

- **Global Trends** : WHO Launches List Of Priority Medical Devices For Management Of Cardiovascular Diseases And Diabetes (July – August 2021)
- **Cover Story** : Re-Invigorating Indian Medical Devices Industry (September – October 2021)  
- Mr K L Sharma, Former Jt. Secretary, Drug & Food Regulation, Ministry of Health & Family Welfer, Government Of India
- **Materials** : Drug Delivery Device Using Polymers With Improved Tribology (September – October 2021)
- **Materials** : Polymers/Biopolymers For Modern Wound Dressing (September – October 2021)
- **Materials** : To Choose PVC In 10 Key Reasons Healthcare Applications (September – October 2021)
- **Global Trends** : Pilot Medical PVC Recycling Scheme In Belgium (September –October 2021)
- **Did You Know ?** : About The Potential Of PVC-Based Medical Device Recycling (September –October 2021)
- **Cover Story** : Importance Of Medical Device Parks And Its Contribution To MedTech Industry Growth (November – December 2021)
- **Cover Story** : Catalytic Role Played By Medical Device Parks And Emerging Scenario In India (November – December 2021)  
- Mr Rajiv Nath, Forum Coordinator, Association Of Indian Medical Device Industry (AiMeD)
- **Cover Story** : Andhra Pradesh MedTech Zone (AMTZ) - Saving Lives, Serving Nation (November – December 2021)  
- Dr Jitendar Sharma, MD & CEO, AMTZ
- **Regulatory** : Stem Cells And Cell Based Products In India : Regulatory Framework (November – December 2021)  
- Dr. A. Ramkishan, Deputy Drugs Controller, CDSCO, East Zone, Kolkata
- **Global Trends** : Polymeric Biomaterials For 3D Printing In Medicine (November – December 2021)
- **Did You Know ?** : About BiPAP Therapy For COPD (November – December 2021)
- **Cover Story** : Medical Plastic Innovations Changing The Face Of Healthcare Industry (January - February 2022)



# Did You Know?

## About Shape Memory Polymers for Medical Applications (SMPs)

These polymers (like shape-memory alloys) will “remember” their original shape when deformed, and flip back to the initial shape when exposed to an external stimulus. The stimuli may be an electric field, light, changes in pH-value, or as most commonly, changes in temperature. Some SMPs even can retain three shapes, their initial (permanent) shape and two deformed morphologies. This effect offers several interesting options.

These polymers have shown great promise in vitro studies as well as in early in vivo studies. Their biocompatibility, and in some cases biodegradability, renders them excellent candidates for minimal invasive surgery and for the design of trigger able biomedical devices.

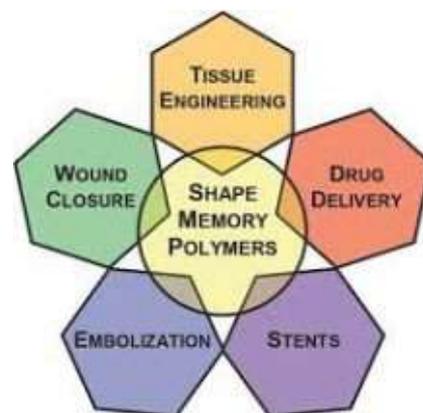
Due to the shape memory effect, the medical devices based on SMP can be implanted into body through minimally invasive surgery in contraction or folded state and recovered to their requisite original shapes at target position.

A commonly known application is bracelets that alter the position of teeth over a period of several months, or coronary stents that the artery and prevent an elastic recoil. The alteration in shape also may be used for clamping.

Feasible are form- and /or force-fitting fastenings. Applications for that are devices such as surgical staplers, remotely controlled switchable implants, or clamps to fix artificial heart valves, using an appropriate sequence of different stimuli, an SMP may perform a periodically repeating movement that may be used as an actuator. Imaginable are valves that may be used as an actuator. Imaginable are valves that open and close automatically according to the surrounding conditions or tool for microsurgery.

While Shape- memory alloys already found widespread applications in medical devices, such as dental wires, cardiovascular stents, or orthopedic implants, the utilization of SMPs still is in its very beginnings.

Ref : 1. “Emerging Trends in Medical Plastic Engineering and Manufacturing” by Markus & Marc 2. <https://www.mdpi.com/2504-477X/7/1/24>



In a Nutshell...

“Medical Device technology is truly interdisciplinary.”

-Chris Toumazou

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From the **Editor's**  
**Desk**



**Plastics for Cardiovascular Devices**

**Cardio Vascular diseases are expected to grow, especially with increase in the ageing population.** Plastics are increasingly being used. The quality of polymers used in such devices includes strength, stiffness, toughness, and dimensional stability. Materials also require biocompatibility, sterilization, sterilization, resistance, durability, strength, and dimensional stability.

This issue includes articles from knowledgeable experts with long experience in Medical Devices and Plastics industries with focus on Cardiovascular Devices.

The lead article by Dr Ajay Padsalgikar on, **“Plastics in Cardiovascular Medical Devices”** gives an very extensive overview on the subject. With about four decades of experience in medical device industry and research, Dr Ajay has 10 patents and published about 30 scientific papers and two books including one on the same subject. The article explains what Cardiovascular Diseases, Cardiovascular system, Plastics used and market for Cardiovascular Devices.

Another lead article by team of scientists from Biomedical Technology Wing, Sree Chitra Institute of Medical Sciences and Technology, Trivandrum – Dr Renjith S and Dr Gijo Raj apart from introducing various **Cardiovascular applications, gives a information on the synthetic polymers used in such applications with a special reference to “TTK-Chitra Heart Valve”** as well as other Cardiovascular Devices.

An article by Ms Rajashri Survane-Ojha gives **regulatory perspective on Cardiovascular Devices** including regulatory concerns. She has also explained how medical device industry professionals can support growth of the industry in India.

One more article by a senior industry professional, Mr Ravi Shankar Srivastava , Managing Director, “Conquest Medtech” **highlights “New Technology and Next Gen Design Vascular Interventional Medical Devices”** including Bio absorbable Stent, Drug Eluting / Drug Deliver Balloon, Heart Valves and more.

Dr T S Kumavel in his analytical article had given elaborate introduction to **Chemical Characterization of Medical Devices.**

The suppliers and contract manufacturers servicing the medical device industry should have good understanding of Medical Device Rules (MDR). An article by Mr Sanjay Shah, Founder, Unikal Consultants in his article on **“Regulatory Issues for Medical Device Supply Chain & Contract Manufacturers”** describes important responsibilities on the part of suppliers and contract manufacturers.

Catheter polymeric tubes are important components in many critical care Cardiovascular Devices. Important aspects related to **“Medical Plastic Catheter Tubes”** are described in an article.

The regular feature article on “Global Medical Device Market” by Mr Amit Dave introduces important characteristics of **“Mexico Medical Devices Market”**. Many critical care medical device require use of **Shape Memory Polymers**. The “Did You Know” column introduces shape memory polymers and their major applications.

Healthcare Plastics end of life is becoming increasingly important. “Global Trends” column gives **Design Guidelines for Hospital Plastics Recycling.**

As always, this issue includes Association, Regulatory & Industry News.

*D.L. Pandya*

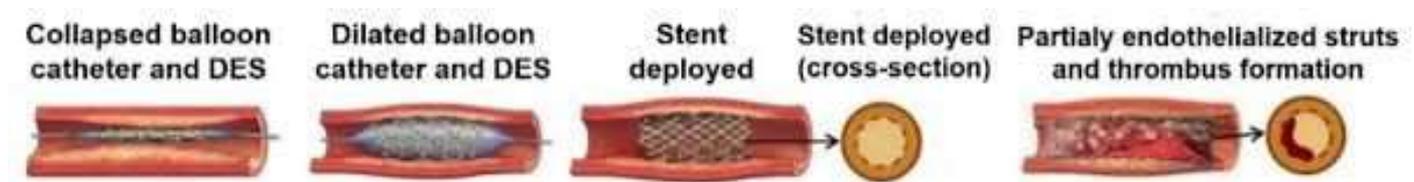
## Medical Plastic Catheter Tubes for Cardiovascular Applications

Cardiology is expected to grow, especially with the increase in the ageing population. Various diagnostic and treatment methods are used in cardiology. The industry growth is attributed to technological advancements, initiatives by various governments & organizations, and the rising incidence of chronic diseases.

As per "Grand View Research", the global cardiac catheters and guide wires market size was estimated at USD 13.9 billion in 2022 and is anticipated to grow at a compound annual growth rate (CAGR) of 7.6% from 2023 to 2030.

Cardiac catheterization is a common method to diagnose or treat a variety of heart problems. For example, the doctor may suggest cardiac catheterization if the patient has :

- Irregular heartbeats, called arrhythmias., Chest pain, called angina, Heart valve problems ,Other heart problems. He / She might need cardiac catheterization if you have, or your doctor thinks you have:
- Coronary artery disease, Congenital heart disease, Heart failure. Heart valve disease.
- Damage to the walls and inner lining of tiny blood vessels in the heart, called small vessel disease or coronary micro vascular disease



During cardiac catheterization, a doctor can:

- Look for narrowed or blocked blood vessels that could cause chest pain.
- Measure pressure and oxygen levels in different parts of the heart.

A catheter is a thin tube made of medical-grade materials used for various medical purposes. It is inserted into the body to treat diseases or perform surgical procedures. Catheters can be placed in different parts of the body, such as cavities, ducts, vessels, the brain, skin, or fatty tissues, depending on the specific medical need. These thin tubes are generally 300–2000 mm long, with a single-lumen (cavity in the tube) or multi-lumen cross-section and a braided or coiled shaft to meet the demands of the application.

Catheters are minimally invasive interventional medical devices actively used in numerous procedures, including stent delivery, drug and contrast injection, imaging guide diagnosis, and ablation

As per "Grand View Research", the global cardiac catheters and guidewires market size was estimated at USD 13.9 billion in 2022 and is anticipated to grow at a compound annual growth rate (CAGR) of 7.6% from 2023 to 2030.

The industry growth is attributed to technological advancements, initiatives by various governments & organizations, and the rising incidence of chronic diseases. COVID-19 had a negative impact on the industry. As a result of COVID-19 emergency cases, hospitals were forced to free up capacity and resources for potential patients, resulting in a considerable decrease in the number of routine & elective procedures, such as cardiac catheterization procedural volume.

### Material Requirements:

Requirements for materials in diagnostic equipment will include

September-October 2024

strength, stiffness, toughness, and dimensional stability. Materials used in implants will require biocompatibility, sterilization, resistance, durability, strength, and dimensional stability.

Catheter tube extrusion is the process of manufacturing catheters and tubing using custom extrusion processes. The process involves applying pressure to the inside diameter (ID) of the catheter to extrude it.

### Catheter tube extrusion:

The extrusion process uses heat and customized dies to draw the material into a tube form with the desired thickness, diameter and determines important characteristics of the catheter's performance such as:

#### • Push

Catheters must possess the right amount of ability to push through the internal anatomy to get to their target sites as intended, a braided shaft lends better push and necessary torque compared to a non-braided one. The latest polymers (e.g. PEEK) and metal alloys (e.g. Nitinol) can offer variations in the characteristics of the catheter.

#### • Flexural stiffness

As heat is applied to the selected catheter material, its physical properties can change and take on corresponding degrees of flexibility. The rate and length of cooling also plays a part in determining the flexibility.

#### • Kink Resistance

Stiffness and kink resistance are undoubtedly connected. So, the manner and temperature of heating and cooling will determine how far the catheter tube is kink resistant. At times the catheter sheath can be co-extruded onto the catheter tube, or it can be added using a slightly different material. This sheath can be braided (more push and torque) or coiled, depending on what characteristic you want.

Striking the right balance in these properties can determine exactly what kind of catheter you will get, not just once, but on a consistent basis. Only experts in polymer science and experts in the field of materials behavior can work out the right balance in the achieving numerous catheter characteristics

### Additional Important Catheter Characteristics

- Hydrophilic catheter coatings – for higher lubricity
- Multi-durometer segments – For better steerability and maneuverability
- Radio-opacity – For better real-time catheter trackability
- Wire options – Flat (lower flexibility) or round (greater flexibility)

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## Plastics in Cardiovascular Medical Devices

**Dr. Ajay D Padsalgikar**

pH.D., Technical Director, Biolinq Inc. USA

### Introduction

With increasing advancement in the field of medical technology, there is a growing understanding of the causes, treatments and care of medical conditions. This increase has also fueled a corresponding increase in the use of medical devices in the treatment of medical diseases. With an increase in the aging population, government involvement and growing economies, the worldwide medical devices market is expected to grow at a rate greater than 5% per annum and reach nearly \$800 billion by 2030 [1]. More than half of the market for medical devices comprises the market for implantable medical devices.

The medical device market in India is still relatively small and in 2016 was estimated to be of the order of ~\$5 billion [2]. This figure is considerably small given the size and population of India, however, the growth rate over the coming years is expected to be more than double the global growth rate. Apart from the low per capita spend by the government on health care; one significant obstacle cited in the growth of the market is the lack of indigenous manufacturing.

Plastics constitute an important part of medical devices and the global market for plastics in medical devices is said to be close to \$10 billion [2]. With growth foreseen in the Devices market, the growth in plastics usage in the devices should at least match that growth. As with the implantable sector in devices, about half of the market for plastics is in the area of implantable devices.

In this article I will be concentrating on the cardiovascular sector, trying to understand the nature of the cardiovascular system, the typical devices used in the cardiovascular area and the role of plastics within them I will highlight the type of plastics have traditionally found usage in this sector. This article covers an assessment of the cardiovascular medical devices market and an explanation of the functioning, role and diseases of the cardiovascular system. It is essential to understand these anatomical/biological aspects in order to effectively appreciate the use of plastics in this area. I have recently published a text *Plastics in Medical Devices for Cardiovascular Applications*, Elsevier, ISBN 978-0-323-35885-9, 2017 [3], and this article will use that text as the primary reference.

### Cardiovascular Medical Devices Market

The cardiovascular medical devices market makes up almost a third of the entire medical devices market, North America accounts for the largest share of the market with 47.1% of the market share in 2013, Europe had a share of 22.6% and emerging markets such as India, China, Brazil, Mexico, South Africa and Russia had a share of 30.3% in 2013, the worldwide

market is expected to grow at greater than 10% annual growth rate with majority of the growth coming from the emerging markets [4].

Within the cardiovascular market, cardiac rhythm management (CRM) devices make up the largest share of the overall cardiac devices market accounting for nearly 35% of the overall market. The cardiac rhythm devices include ECG devices and cardiac monitors for diagnostic applications, implantable pacemakers, defibrillators and cardiac resynchronization devices for treatment of cardiac arrhythmia. The overall CRM market is expected to grow at 4.7% per annum [5]. The strongest growth in the CRM sector is expected to be in the diagnostic sector and within the devices sector the fastest growth is expected in defibrillators.

The entire worldwide catheter market is expected to grow at a rate 7.5% per annum; by 2020 the market size is estimated at \$42.5 billion [6]. Cardiovascular catheters make the majority of the overall catheters market in terms of revenue accounting for nearly 40%. It is forecast that the two fastest growing segments of the market during this period will be advanced diagnostics and advanced ablation, with growth rates of 23% and 17% respectively [7]. These segments will be driven by growth in the number of atrial fibrillation ablation procedures - atrial fibrillation is the commonest sustained arrhythmia in North American and European patients and was classified as a growth industry in the 21st century by the European Heart Journal even in 2000 [7].

The market for prosthetic heart valves was worth \$4.8 billion in 2020 with an annual growth rate of 9.1% [8]. The rise of valvular diseases in an ageing population is the main driver for this growth and the introduction of the minimally invasive technique for heart valve replacement is expected to be the strongest area of growth.

The market for the treatment of coronary heart disease using angioplasty and stent technologies is estimated to grow to \$22.5 billion by 2021 [9]. The market for stents is large and is expected to grow to greater than \$10 billion worldwide by 2021. The number of patients receiving stent grafts for aneurysm repair is \$1.9 billion in 2020 and expected to grow at a rate of between 6.7 and 9.5 % per annum [10].

### Cardiovascular System

The cardiovascular system in the human body is the primary organ system that is responsible for the circulation of blood and nutrients to and from the cells and tissues in the body. The complex cardiovascular network is illustrated in figure 1. In the cardiovascular system, blood carries with it the nutrients and oxygen to the cells and carries from it metabolic waste products and carbon dioxide. Blood is composed of cells suspended in plasma. Plasma constitutes about 55% of the blood fluid and is

composed of more than 90% by water and also contains dissolved proteins, ions, hormones and blood cells. Blood cells are composed of red blood cells or erythrocytes (RBC), white blood cells or leukocytes (WBC) and platelets. RBCs are the most abundant cells present in the human blood. The RBC contain hemoglobin, the hemoglobin is an iron containing protein that shows a great affinity for oxygen and it is this affinity that is responsible for the efficient transport of oxygen along with the blood to various parts of body. The hemoglobin is what gives blood its characteristic red color, when the hemoglobin contains oxygen, the blood is bright red and when it is de-oxygenated it turns dark red. WBCs comprise the main constituents of the body's immune system and help in fighting all infectious diseases and foreign invaders inside the body. The main function of platelets, also known as thrombocytes, is to stop any bleeding associated with injury to the blood vessels by clotting blood flow.

With the aid of blood circulation, the cardiovascular system can be said to perform four main functions:

- Transport of nourishment to the cells and waste products from the cells
- Maintenance of body's immune system
- Stabilize body temperature and pH
- Maintain bodily stability or homeostasis

## Structure of the Cardiovascular System

The heart is the center of the human cardiovascular system. The anatomy of the heart is illustrated in figure 2. The human heart is a four chambered pumping device that functions as the central organ for the circulatory, cardiovascular system within the body. The heart can be further divided into the right and left sides where the right side receives used, deoxygenated blood from the various organs of the body and delivers it to the lungs for re-oxygenation.

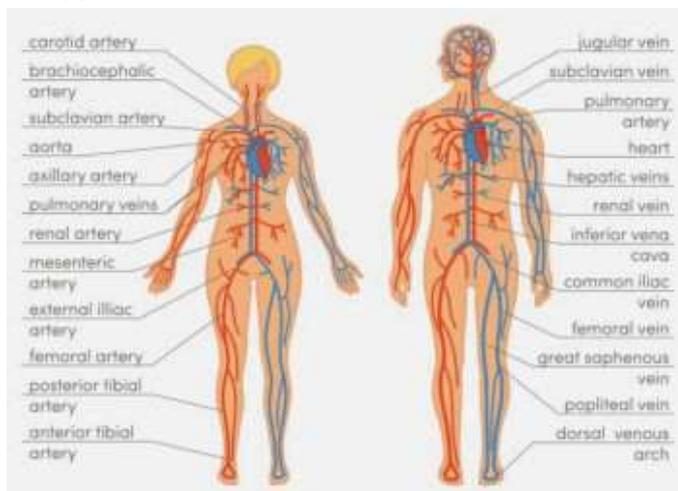


Figure 1: Cardiovascular system of the human body

The left side of the heart receives oxygenated blood from the two lungs and pumps it to the various organs, tissues and cells of the body.

The structure of the heart is composed of four distinct chambers and four valves. The two upper chambers are termed atria and act as receiving chambers, receiving the blood coming in to the heart from outside the heart. The right atrium, receives the deoxygenated blood from the body, whereas the left atrium receives oxygenated blood from the lungs. The atria transfer their contents into the corresponding lower chambers. The two lower chambers are termed ventricles and act as the pumping chambers of the heart. The right ventricle, that receives the contents of the right atrium, pumps deoxygenated blood to the

lungs for re-oxygenation. The left ventricle, on the other hand, receives blood from the left atrium and pumps this oxygenated blood to the entire body.

The upper and lower chambers, on each side, are connected to each other through one way valves. These valves ensure that the blood flows only from the atrium to the ventricles and there is no regurgitation or leakage. The right atrium is connected to the right ventricle through the tricuspid valve. The left atrium is connected to the left ventricle through the mitral valve. One way valves are also present in the pathway of the blood as the ventricles pump their contents. As the right ventricle pumps the deoxygenated blood to the lungs, the valve that controls this flow is termed the pulmonary valve. As the oxygenated blood makes its way to the rest of the body with the pumping action of the left ventricle, this flow is regulated by the aortic valve.

The oxygenated blood is pumped by the left ventricle through the blood vessels to all organs, tissues and cells of the body. The used, deoxygenated blood travels back to the heart for the right ventricle to pump this to the lungs in order to re-oxygenate the blood. This entire circuit is the cardiovascular system of the body. The blood vessels that transport blood away from the heart are termed arteries and the ones that take blood towards the heart are called veins. From the left ventricle blood is pumped into the main artery called the aorta. The aorta branches into numerous smaller arteries. When the blood from the arteries reaches its destination, the arteries are further divided into smaller arterioles and then into capillaries measuring 5-10 micrometers in diameter. It is in the capillaries that the exchange of substances occurs between the blood and the cells. Blood flows out of the organs and returns to the heart by the way of veins. The blood returns to the heart from the lower part of the body with the vein called the inferior vena cava, and from the upper part of the body with the superior vena cava.

## Heart Anatomy

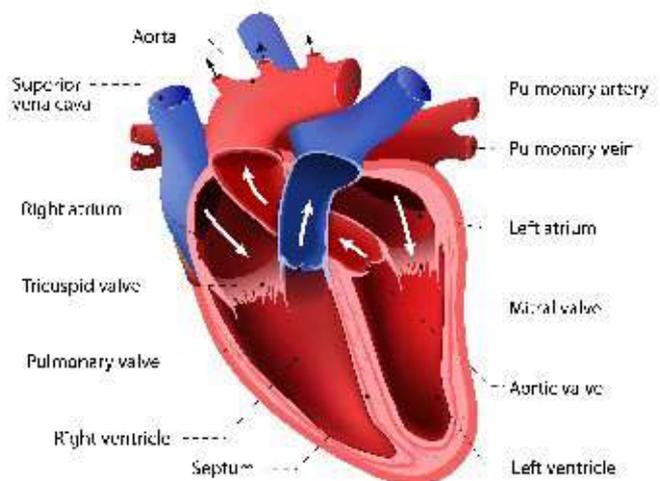


Figure 2: Anatomy of the heart

## Cardiovascular Diseases

As we have seen the criticality of the entire cardiovascular system, any deviation from the normal conditions can lead to a diseased circulatory system and subsequent development of cardiovascular diseases. Cardiovascular diseases are the leading cause of death globally. This is true in all areas of the world except Africa. Together they resulted in 17.3 million deaths (31.5%) in 2013 up from 12.3 million (25.8%) in 1990 [3]

As a result of being the leading cause of mortality, the risk factors for cardiovascular diseases have been thoroughly investigated in many studies [3]. Several risk factors that are associated with

cardiovascular disease. It is said that more than 90% of the deaths caused by cardiovascular diseases are preventable.

The management of the risk factors mentioned earlier through proper diet, exercise, eliminating tobacco and limiting alcohol intake is shown to be successful in reversal of cardiovascular diseases in many patients in several studies [3].

Cardiovascular diseases can be broadly classified as the diseases affecting the heart and the diseases affecting the blood vessels.

Diseases directly affecting the heart muscle are:

- Valvular disease
- Heart failure
- Cardiac arrhythmias

The diseases affecting primarily the blood vessels in the cardiovascular system are:

- Coronary artery disease
- Peripheral arterial disease
- Aortic aneurisms

## Cardiovascular Medical Devices and Plastics

Plastics have an inherent advantage over traditionally used materials, such as glass and metals, in medical devices. Plastics are lightweight, inexpensive and often compatible with bodily fluids. Most plastics are also comparable in density to the body and thus are easier to be incorporated into the body. They, for the most part, also have a high degree of resistance to chemicals, both natural and synthetic, that make them suitable to be used in medical applications.

Plastics can also be formulated with a myriad of different chemistries. They can be soft or hard, elastomeric or rigid, thermoplastic or thermoset etc.

They can also be formulated as biologically stable or degradable. A stable formulation is one that can resist the action of body fluids and can be inert, making them suitable for the construction of long-term implants. A degradable formulation, on the other hand, can be broken down into easily digestible and harmless elements over time. The degradation can be programmed to occur either at a specific time or upon a specific action. This makes biodegradable plastics attractive options in areas such as drug-device combinations and regenerative medicine.

The use of plastics in medical applications spans a wide spectrum of applications. Many plastics form a part of medical disposables such as wipes, bandages, syringes, tubes, blood bags, packaging materials etc. As the name suggests, these are discarded after a single use in a medical procedure. They do come in short-term contact with medicines and/or the human body.

The use of plastics has revolutionized the area of medical diagnostics. Whether it be in simple blood pressure measurement devices or the much more complex Magnetic Resonance Imaging (MRI) machines, plastic materials offer many advantages in the construction of this equipment such as design flexibility, light weight, robustness etc., this has enabled the doctors to diagnose the patient's condition accurately and monitor the progress of any condition. Often these diagnostic equipment work outside the body and remain external.

The majority of medical devices are made to be implantable systems. These devices are implanted inside the human body and perform critical functions either in the area of drug delivery or regulation of some bodily function. Plastics form the core of many of these devices, and the properties of the plastic material allow greater functionality of the device.

The implantable devices are further divided into short term

implantable and long term implantable devices depending on the duration of the dwell time of the implantable device inside the body. Most devices shorter than a 90 day dwell time are classified as being short-term implants. Biological stability becomes an important consideration for long term implantables.

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## Biography of Ajay D Padsalgikar

Ajay graduated with a degree in Polymer Engineering from the University of Poona, India in 1990. He then completed a PhD from Clemson University, SC, USA in 1996. Ajay has worked different companies, Huntsman Polyurethanes in Belgium, AorTech Biomaterials in Australia and Abbott in Minnesota, DSM Biomedical, Pennsylvania. He has been involved with different aspects of polyurethane chemistry, morphology and processing of polyurethanes for medical devices.

Ajay joined Biolinq Inc. in July 2022 as a Technical Director, where he is working on a range of material solutions for biosensors.

Ajay has more than 30 published scientific papers and 10 patents. He has also authored two books, 'Plastics in Medical devices for Cardiovascular Applications' was published by Elsevier. 'Applications of Polyurethanes in Medical Devices' was published in June 2022 also by Elsevier.



Dr. Renjith S



## Polymers For Cardiovascular Applications

Dr. Gijo Raj

Biomedical Technology Wing, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Poojappura, Trivandrum 695012.

Cardiovascular disease (CVD) is a broad umbrella that encompasses many abnormalities associated with the heart (cardiac) and associated circulatory (vascular) systems. CVD accounts for one of the major causes of deaths reported worldwide. As per recent statistics from WHO, more than 30 % of global mortality is due to CVD. Among CVD, myocardial infarction and stroke are the major culprits accounting for nearly 90% of CVD deaths. Thus, profound research interest exists in the early diagnosis and management of CVD. Cardiovascular devices are a class of medical devices used to diagnose, treat, and mitigate CVD. Common examples include cardiac stents, valves, cardiac patches, annuloplasty rings, vascular grafts, atrial septal defect closure devices, and radiopaque agents for imaging atherosclerosis.

Commercial production of medical-grade polymers has brought a transformative change in the implantable cardiovascular devices industry owing to their stability, mechanical strength, and the capability to impart appropriate host tissue response. Flexibility combined with the elastic nature of these materials makes them suitable candidates for minimally invasive trans-catheter procedures. Polymers of different categories such as homopolymers, copolymers, natural polymers, synthetic polymers, blends, composites, etc. have been employed for various cardiovascular devices. Below is an overview of different polymeric systems utilized in various cardiovascular devices.

**Natural polymers:** Because of their biocompatibility and biodegradability, they are often accepted for developing biomedical devices. Besides, natural polymers often have excellent mechanical properties suitable for various device applications. Gelatin, collagen, silk, and alginate are natural polymers mostly reported to have applications in cardiovascular devices. Howard et. al, employed collagen fibre-reinforced collagen scaffolds for cardiac valve development. Gelatin and silk-like natural polymers are often used for developing tissue-engineered composites to be used as cardiac patches for repairing cardiac tissue damage.

**Synthetic polymers:** Synthetic polymers developed by chemical synthesis pathways provide the opportunity to tune the structural and physicochemical properties required for the designated application. They are used immensely to develop various cardiovascular devices such as vascular grafts, cardiac patches, cardiac valves, stent coatings, total artificial heart, etc.

Depending on the nature of their application, synthetic polymers are classified into biostable and biodegradable or bioerodable polymers. For example, Chitra-TTK mechanical heart valves (Fig. 1) consist of biostable polymers such as ultra-high molecular weight polyethylene (UHMWPE) tilting disc, and Polyethylene terephthalate (PET) fabric for suturing the valve to the adjacent tissue. These two polymers are intended to be stable in the body and perform their function for long periods of time (up to several decades). However, biodegradable polymers are intended to degrade through bulk or surface erosion mechanisms over a period of time. They are stable in the body only for a short duration (few weeks to few months). Biodegradable polymers are mostly used in drug delivery applications. For example, Poly (L-Lactic acid) is widely used in drug-eluting stents. The rate of biodegradation can be controlled by tuning the number of hydrolytically cleavable ester bonds in the polymer chain. Hence polylactic-co-glycolic acid copolymers are often used to increase the rate of biodegradation.



Fig. 1. TTK-Chitra heart valve.

(Image courtesy: <https://dst.gov.in/low-cost-sree-chitra-valve-facilitating-governments-commitment-inclusive-healthcare-all>)

**Dr. Renjith S.** obtained his PhD in Chemistry from CSIR-NIIST under the supervision of Dr. J. D. Sudha. He is currently a Scientist C at the Central Analytical Facility in the Department of Technology and Quality Management, Biomedical Technology wing, Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST). His major areas of interest are the analytical evaluation of biomaterials and biomedical devices, ionic liquid-based smart and sustainable biomaterials, electrochemical bio-sensing, corrosion studies of medical devices, extractable and leachable (E&L) analysis of medical devices, and antimicrobial surface modification of polymeric medical devices.

**Dr. Gijo Raj** obtained his PhD from the Universite de Bretagne Sud, in Lorient France under the guidance of Prof. Yves Grohens. He is currently Scientist C at the Division of Polymeric Medical Devices, Department of Medical Devices Engineering, Biomedical Technology Wing, Sree Chitra Tirunal Institute for Medical Sciences and Technology Trivandrum. His areas of research are Polymers and Composite materials for medical applications, Polymer processing, Filament extrusion for Fused Deposition Modelling, antimicrobial coatings, Surface and Interface studies using Atomic Force Microscopy and Quartz Crystal Microbalance with Dissipation.

## Heart valves:

Heart valves are an important part of the flow regulatory mechanism of the human circulatory system and their malfunctioning will be fatal. As per recent statistics, valvular heart disease is the most prevalent heart disease across the globe. Surgical replacement of defective valves with mechanical or bioprosthetic heart valves proves to be an effective treatment modality. The active parts of the mechanical heart valve such as the valvular leaflet and the fabric around the metal frame are made of polymers. Bioprosthetic valves rely on the favourable mechano-dynamic properties of biopolymers. Recently researchers around the globe have been exploring to design of all-polymer heart valves. Even though many polymers tried during the last few decades most of them failed during pre-clinical stages due to poor biocompatibility, mechanical properties, and high calcification rates. The search for suitable polymers for all-polymer heart valves is still going on.

Apart from cardiac valves, other lifesaving medical devices/combinations like extracorporeal membrane oxygenation (ECMO), and left ventricular assist device (LVAD) are also composed of various polymeric components. Different types of synthetic polymers were used for developing artificial blood vessels known as vascular grafts. Poly (ethylene terephthalate) (PET) was used for developing vascular grafts for the first time in 1954. Later polymers like expanded poly(tetrafluoroethylene) (ePTFE) and polyurethanes (PU) were also reported for developing vascular grafts. Blood compatibility, anti-thrombosis, and anti-haemolytic properties are required for the successful functioning of the vascular graft. Besides, the water-impermeable coating formed through vapor phase deposition of inert polymers such as Parylene C is used to coat cardiovascular devices viz. pacemakers to prevent damage caused due to the ingress of water molecules into electronic circuits. In short, polymers have a significant role to play in the development of cardiovascular medical devices.

Unlike conventional polymers for industrial use, polymers for medical applications should meet and qualify stringent criteria such as appropriate host response, biocompatibility, non-toxic, appropriate design, manufacturability, and adequate mechanical properties. Consequently, commercial synthesis and manufacturing require rigorous quality control in every step of commercial production. This makes medical-grade polymers, especially implant grades 100 to 200 times more expensive than polymers for industrial applications. Hardly any medical-grade polymers are commercially manufactured in India. For example, polylactic acid (PLA) is a biodegradable polymer. Its commercial-grade costs ~ Rs. 450 per Kg (as of 2024) and is mostly used as an eco-friendly alternative sustainable material for disposable cups, plates, etc. However, medical-grade PLA as well as industrial-grade PLA are both imported and are highly expensive. Polyethylene terephthalate (PET) yarns are used to make PET fabric that is used in several cardiovascular devices such as mechanical heart valves, and vascular grafts. Medical-grade PET yarns with material safety data are mostly imported. Some Indian industries manufacture textile-grade PET yarns that are used to make PET fabric. However, they must undergo rigorous testing for biocompatibility evaluation as per ISO 10993, and preclinical studies, to meet regulatory requirements before any clinical trials and commercialization activities. Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum is a Central Drugs Standard Control Organization (CDSCO) approved medical device testing laboratory for testing and

evaluation of medical devices on behalf of the manufacturer under the Medical Devices Rules, 2017. About twenty biological tests (mostly biocompatibility tests based on ISO 10993) are accredited by the French Accreditation Committee (COFRAC) of France.

Concerted efforts from Industry, policy makers, and stakeholders are the need of the hour for enabling the manufacturing of medical-grade polymers in India. Indian Medical Device Policy 2023 underlines the importance of domestic investments and indigenous production of raw materials for the holistic growth of the Indian medical device sector. As India is one of the largest markets for medical devices, manufacturing medical-grade polymers would greatly reduce our dependence on the import of expensive medical-grade polymers and hence advanced health care would become more accessible to millions in need. It would assist the Indian efforts to achieve 10-12% of the global medical device market share by the coming 25 years, the proposed objective of Medical Device Policy 2023.

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## Cardiovascular Devices - A Regulatory Perspective

### Rajashri Survase-Ojha

Founder & Director  
Raaj GPRAC Pvt. Ltd. Mumbai

Ms. Rajashri Survase-Ojha is one of the leading professionals in India with extensive expertise in the Pharmaceuticals, Nutraceuticals, and Medical devices industries with more than 3 decades of qualifications as an R&D scientist, and CMC expert, and experience in the Development & Implementation of QMS processes in Medical devices. She has worked with renowned organisations.

**In a free-wheeling interview to “Medical Plastics Data Service”, apart from sharing her journey, she has explained current developments in the Cardiovascular area, their regulatory concerns, regulatory reforms for medical device sector in India as well as how professionals can provide the Indian Medical Device Industry with the specialized skills, cost-efficiency, budget clarity and innovative solutions needed to drive successful project outcomes.**

#### Q. The focus of this issue of the Magazine is Cardiovascular devices. Kindly inform your views on the current developments in the CVS area.

##### Rajashri :

According to current ESC guidelines, heart failure can be separated into heart failure with preserved ejection fraction (LVEF > 50%; HFpEF), mid-range EF (LVEF 40–49%; HFmrEF) and reduced ejection fraction (LVEF < 40%; HFrHF). The cause of death in patients suffering from heart failure is not only a result of hemodynamic failure but also suddenly and unexpectedly occurring from ventricular electrical disturbances such as ventricular tachycardia and -fibrillation. Implantable cardioverter defibrillators (ICDs) represent the only available tool in our treatment armamentarium proven to prevent arrhythmic sudden cardiac death. In addition, cardiac resynchronization therapy (CRT) is an established treatment option significantly improving both quality of life as well as mortality.

In spite of these proven benefits, both ICD as well as CRT therapy remain underutilized in many countries. The reasons are

manifold. It will also be worth mentioning some remarks about Implantable Cardioverter Defibrillator (ICD) Therapy in Patients Suffering From Chronic Heart Failure (CHF)—Of Primary and Secondary Prevention, in Ischemic and Non-ischemic Cardiomyopathy.

Patients with heart failure and reduced ejection fraction (LVEF < 35%) are at an increased risk of sudden cardiac death due to ventricular arrhythmias. This risk is highest in those who already suffered from previous ventricular arrhythmic events. In this “secondary prevention” situation where no reversible cause such as an acute myocardial infarction can be identified, an ICD is recommended with a class IA indication (if survival > 1 year with good functional status is predicted) according to ESC guidelines.

To conclude, implantable devices such as ICDs and CRTs are a cornerstone in the modern treatment of heart failure patients, reducing morbidity and mortality in this population. Continuing medical education regarding the pathophysiology, epidemiology, clinical trial results and novel technologies are of paramount importance to optimize patient selection and individual benefit.

Ms. Rajashri Survase-Ojha has a background in pharmacy and extensive expertise in the Pharmaceuticals, Nutraceutical, and Medical devices industries. With more than 3 decades of qualifications as an R&D scientist, and CMC expert, and experience in the Development & Implementation of QMS processes in Medical devices, 510[k], CE marks, MDSAP, Qualifications, and Validations of Equipment, Water systems, HVAC system, Technology transfers till Global regulatory approvals etc, Ms. Rajashri has worked with renowned organisations like SANDOZ, GLENMARK, TCS, NOVARTIS, COGNIZANT, FAMYCARE, SYNERGY, SPECTRUM Pharmatech, etc. Moving forward, Ms. Rajashri has been dedicated to the role of a Consultant, Auditor, and Trainer for the past 15 years. She is passionate about grooming future leaders, designing courses for professionals at all levels, and actively involved in Audits & Compliance activities in the pharma and medical devices industries. She has successfully handled more than 300 man-days of Audits at national and Global levels, with more than 3000 Regulatory submissions to different health authorities. She has trained more than 45000 candidates to date.

**Rajashri Survase-Ojha**, Founder & Director [DIN-07058128], Raaj GPRAC PVT. LTD. GxP, Global RA Consultant, Auditor, Trainer, Lead Auditor ISO;13485-2016, ISO;9001-2015, ISO/IEC-17025-2017, FSSC-22000,V-6

Ongoing and future studies and technological advances are aiming to improve patients' prognoses even further. Their implementation, however, will be the task of all stakeholders involved including cardiologists, general practitioners and—increasingly importantly—the patient him/herself. Only by a collaborative effort will we be able to move the field forward, and to further develop concepts to improve the prognosis of patients with heart failure.

It is worth mentioning the role of smart wearables in the current CVS disease management. The healthcare sector continues to leverage the power of smart wearables for the detection and prediction of cardiovascular diseases (CVDs), the leading cause of death globally. A recent systematic literature review analyzed key criteria, highlighting the efficiency of smart wearable devices in managing CVDs. Results indicate the growing interest in this area, emphasizing the need for further research to enhance the effectiveness of these devices.

**Q. Please explain about the Regulatory concerns for CVS devices to our readers.**

**Rajashri:**

Regulatory compliance is key in the medical industry, ensuring innovation efficiency and user safety. The new EU and Indian-MDR-2017 Medical Device Regulation bring challenges and opportunities. By following a structured market approval process, including regulatory strategy planning and post-market activities, the balance between benefits and risks is maintained. Essential evidence is provided through controlled documentation and procedures as per ISO 13485-2016 & ISO 14971-2019.

Cardiovascular disease (CVD) is a global health concern, impacting millions annually. Smart technologies have transformed CVD management, offering real-time monitoring and personalized treatment. Challenges like data privacy persist, but the future of smart technologies in CVD management looks promising. Advancements in telemedicine and bio fabrication are paving the way for more efficient and personalized care. Explore the evolving landscape of smart technologies in CVD management and their potential to shape healthcare's future.

**Q. Some cardiac devices involve medical products, and this makes the situation complicated as medicines may be treated under a different set of laws. Your opinion on these drug-device combinations please.**

**Rajashri:**

Drug-device combination products are revolutionizing the field of implantable medical devices, addressing long-standing challenges associated with implantable medical devices. From pacemakers to orthopaedic implants, these products are improving patient outcomes and quality of life. We have to shed light on the critical aspect of drug-device interactions, highlighting scenarios where the use of certain drugs may necessitate the placement of a pacemaker. This intersection of medicine and technology underscores the complexity and innovation within the healthcare industry.

**Q. The regulatory landscape in the medical device industry has been evolving since 2018, shaping the way companies operate. A recent survey revealed that an equal number of companies prefer internal teams or consultants. Your views on this dilemma, please.**

**Rajashri:**

Hiring external consultants can provide your company with the specialized skills, cost-efficiency, budget clarity, and innovative solutions needed to drive successful project outcomes.

Change is a constant in the business world, and navigating it

effectively is key to success. External consultants play a crucial role in this process, offering several advantages to organizations. Hiring external consultants can bring valuable benefits to any company due to many reasons like

**1. Fresh eyes on the problem:**

- Diverse Perspectives: External consultants bring innovative solutions from various industries.
- Benchmarking Best Practices: They compare your practices with industry leaders for successful strategies.

**2. No office politics:**

- Neutral viewpoint: They provide unbiased recommendations without internal biases.
- Conflict resolution: Consultants can mediate conflicts objectively, ensuring decisions benefit the organization.

**3. Experts at your service:**

- Access to specialized knowledge: Consultants offer expertise in specific areas like IT, HR, etc.
- Flexibility in service: External consultants provide tailored solutions to meet project needs and timelines effectively.

Considering these advantages, hiring external consultants can be a strategic move for your company's growth and success.

**4. Specialized Attention:**

External consultants bring focused expertise to your project, offering undivided attention and specialized knowledge in a particular field or industry.

**5. Cost Savings:**

While the initial expense may seem high, hiring external consultants can be cost-effective for large companies in the long run. You only pay for the specific project work, with no ongoing salary or benefits costs.

**6. Clarity in Budgeting:**

Working with external consultants allows for a predefined budget and fixed project costs. Detailed expense breakdowns and flexible payment schedules provide transparency and help make profitable decisions.

**7. Learning Opportunities:**

External consultants offer diverse exposure and fresh perspectives, bringing innovative solutions to your business challenges. Take advantage of their expertise to enhance your projects.

**8. Adaptation to market trends:**

External consultants specialize in staying ahead of the curve, analyzing market shifts, and recommending strategies that align with industry trends. This proactive approach positions businesses to seize new opportunities promptly.

**9. Innovation:**

Professional consultants provide tailored solutions that cater to specific organizational needs, fostering innovation as a practical tool for driving meaningful change within the company.

**10. Collaborative growth:**

External consultants collaborate with internal teams to analyze, plan, and implement strategies aligned with organizational goals. This partnership approach ensures a united front towards growth.

When choosing between internal and external consultants, the latter often proves advantageous. By avoiding internal politics and offering valuable insights, external consultants bring expertise and efficiency that can give businesses a competitive edge. Considering factors like team dynamics and the services consultants provide can help in making the right choice for your organization's growth.

## Q. How do you see the future evolution of the laws in India?

**Rajashri:**

The medical device industry is on a rapid growth trajectory, with the World Health Organization identifying over 2 million medical devices across 7,000 groups. By 2025, the industry is projected to reach a staggering \$612 billion, emphasizing the need for consultants in navigating increased regulatory scrutiny. This dynamic field not only offers the chance to impact lives globally but also to travel the world representing cutting-edge innovations.

In India, the Medical Device Industry is poised for exponential growth, projected to reach \$50 billion by 2030 and potentially \$250 billion by 2047. The diagnostics segment is expected to lead this growth, according to industry experts. With evolving regulations such as the requirement for MD-14/MD-15 Import License for certain medical devices, understanding the regulatory landscape is crucial for market entry and compliance.

The future of Indian healthcare is shifting towards a personalized, digitized, and preventative model. The Indian Medical Device Rules and subsequent amendments are reshaping the industry, presenting challenges and opportunities for manufacturers. Understanding the role of the Central Drugs Standard Control Organization (CDSCO) and the implications of regulations is key, especially given concerns surrounding high-risk devices.

The integration of drug-device combination products is revolutionizing implantable medical devices, improving patient outcomes from pacemakers to orthopaedic implants. Highlighting the significance of drug-device interactions, these innovations underscore the complexity and innovation within the healthcare industry. Stay informed to navigate this ever-evolving landscape effectively.



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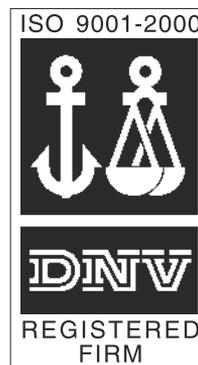
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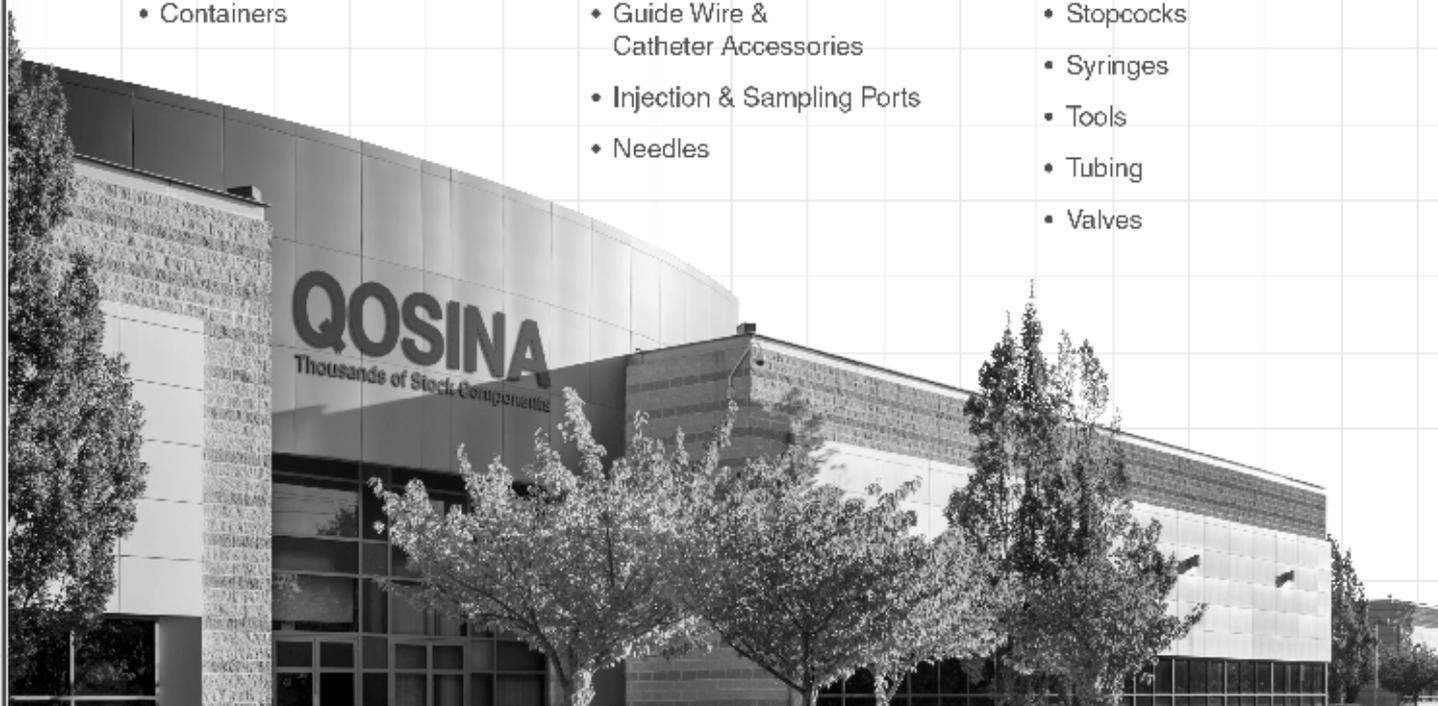
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Society Of Plastics Engineers ( SPE ) is a global leader with presence in 84 countries and having 60,000 plus stakeholders founded in 1942 with an objective of uniting professionals worldwide through knowledge sharing, networking, training, events etc.

The Medical Plastics Division (MPD) exists to encourage the Interchange of technical and regulatory information on the polymer materials/components used in medical devices and in device containers among the scientists and engineers who are working in medical device and related industries.

For more details, please send your name / email / contact address to [medicalplastics@gmail.com](mailto:medicalplastics@gmail.com)

In light of the negative attention surrounding the term "plastics" it is crucial to remind ourselves of the multitude of benefits plastics offer. To reaffirm this, we have compiled a comprehensive list of 100 benefits of utilizing plastics in medical devices, which you will find in the following section.

**Please note that while plastics offer numerous benefits in medical devices, each specific application and device design should be thoroughly evaluated and validated for safety, efficacy, and compliance with regulatory requirements.**

## 100 Benefits of Plastics in Medical Devices

### 1. **Biocompatibility:**

Plastics can be engineered to be biocompatible, ensuring compatibility with living tissues and minimizing the risk of adverse reactions or tissue damage.

### 2. **Lightweight:**

Plastic materials are lightweight, making medical devices more comfortable for patients to use and reducing the strain on healthcare professionals during procedures or treatments.

### 3. **Versatility:**

Plastics offer a wide range of properties and can be molded into various shapes, sizes, and forms, allowing for the production of diverse and customized medical devices.

### 4. **Durability:**

Plastics are durable materials that can withstand rigorous use, repeated cleaning or sterilization processes, and mechanical stress, ensuring the longevity and reliability of medical devices.

### 5. **Transparency:**

Certain plastics are transparent, enabling healthcare professionals to easily monitor fluid levels, detect blockages, or observe the condition of tissues during medical procedures.

### 6. **Cost-effectiveness:**

Plastics are generally more cost-effective than alternative materials, such as metals or ceramics, making medical devices more affordable and accessible to healthcare providers and patients.

### 7. **Resistance to corrosion:**

Plastics are resistant to corrosion, reducing the risk of degradation or contamination when medical devices come into contact with bodily fluids or undergo sterilization.

### 8. **Electrical insulation:**

Plastics provide excellent electrical insulation properties, preventing unwanted electrical conductivity and ensuring the safe operation of medical devices that incorporate electrical components.

### 9. **Sterilizability:**

Many plastics can be easily sterilized using common methods such as steam, ethylene oxide (EtO) gas, or gamma radiation, maintaining a high level of cleanliness and minimizing the risk of infection.

### 10. **Chemical resistance:**

Plastics exhibit resistance to a wide range of chemicals, protecting medical devices from potential chemical interactions and maintaining their integrity and functionality.

### 11. **Flexibility:**

Plastics can be designed to be flexible or elastic, allowing for the production of medical devices that conform to the body's contours, such as catheters or wound dressings.

### 12. **Low friction:**

Certain plastics have low friction coefficients, reducing the risk of tissue damage or discomfort during medical procedures that involve the insertion or movement of devices within the body.

### 13. **Multi-Component Integration:**

Plastics allow for the integration of multiple components within a single molded part, reducing the need for assembly and potential points of failure in complex medical devices.

### 14. **Recyclability:**

Many medical-grade plastics are recyclable, contributing to sustainability efforts by reducing waste and resource consumption in the production of medical devices.

### 15. **Ease of fabrication:**

Plastics can be easily fabricated using a variety of techniques such as injection molding, extrusion, or 3D printing, enabling efficient and scalable manufacturing of medical devices.

### 16. **Customizability:**

Plastics offer a high degree of design flexibility, allowing for the creation of complex geometries or the integration of multiple functions within a single medical device.

### 17. **Reduced risk of contamination:**

Plastics can be produced with smooth and non-porous surfaces, minimizing the risk of bacterial or fungal growth and facilitating easier cleaning and disinfection.

### 18. **Compatibility with imaging techniques:**

Plastics can be engineered to have minimal interference with medical imaging techniques such as X-rays, CT scans, or MRI, ensuring accurate diagnosis and monitoring.

### 19. **Reduced allergenic potential:**

Plastics can be selected or modified to minimize allergenic reactions, making them suitable for use in medical devices that come into direct contact with the skin or body fluids.



# SPE INDIA Medical Plastics Division

## 100 Benefits of Plastics in Medical Devices



### 20. Innovation and advancement:

The use of plastics in medical devices has spurred innovation and advancements in healthcare, enabling the development of novel technologies and improving patient outcomes through enhanced diagnostics, treatments, and patient care.

### 21. Flexibility in design:

Plastics can be easily molded into intricate shapes, allowing for the creation of complex medical devices that fulfill specific functions or fit unique patient needs.

### 22. Bio-inertness:

Some plastics are bioinert, meaning they do not react with bodily tissues or fluids, reducing the risk of inflammation or immune responses when used in medical devices.

### 23. Resistance to stress cracking:

Plastics can be engineered to be resistant to stress cracking, ensuring their structural integrity even under high stress or strain, making them suitable for load-bearing applications.

### 24. Easy sterilization validation:

Plastics can be sterilized using standard methods, and their compatibility with various sterilization techniques makes validation of the sterilization process easier.

### 25. Resistance to degradation:

Plastics can withstand exposure to environmental factors such as UV radiation, humidity, or temperature variations, ensuring the long-term stability and performance of medical devices.

### 26. Radio-opacity:

Some plastics can be made radio-opaque, allowing them to be easily visualized under X-ray or fluoroscopy, aiding in device placement or monitoring during medical procedures.

### 27. Ease of assembly:

Plastics can be designed with features that facilitate easy assembly, reducing manufacturing complexity and enabling efficient production of medical devices.

### 28. Anti-static properties:

Plastics can be formulated to have anti-static properties, preventing the buildup of static electricity and minimizing the risk of electrostatic discharge in sensitive medical environments.

### 29. High strength-to-weight ratio:

Plastics can offer high strength while being lightweight, allowing for the production of sturdy yet portable medical devices, such as portable diagnostic equipment or wearable devices.

### 30. Smart Material Properties:

Plastics can be engineered as "smart" materials that respond to external stimuli, enabling the development of devices with adaptive functionalities, like controlled drug release based on physiological conditions.

### 31. Impact resistance:

Plastics can be engineered to have high impact resistance, making medical devices more robust and able to withstand accidental drops or impacts during use.

### 32. Low thermal conductivity:

Plastics have low thermal conductivity, reducing heat transfer and minimizing the risk of thermal discomfort or burns when medical devices come into contact with the skin.

### 33. Enhanced drug delivery:

Plastics can be used in drug delivery systems to control the

release of medications, ensuring precise dosing, and improving therapeutic outcomes.

### 34. Non-magnetic properties:

Unfilled thermoplastics are non-magnetic, making them suitable for medical devices used in environments where magnetic fields, such as MRI rooms, are present.

### 35. Reduced risk of allergic reactions:

Plastics can be selected or modified to be hypoallergenic, minimizing the risk of allergic reactions in patients with known sensitivities or allergies.

### 36. Compliance with regulatory requirements:

Plastics used in medical devices can meet regulatory standards such as biocompatibility, sterility, or chemical resistance, ensuring compliance with safety and quality regulations.

### 37. Integration of electronics:

Plastics can be designed to incorporate electronic components, enabling the development of advanced medical devices with integrated sensors, displays, or wireless communication capabilities.

### 38. Flexibility in color options:

Plastics offer a wide range of color options, allowing for color-coded medical devices, which aid in easy identification, organization, or differentiation of various devices.

### 39. Improved patient comfort:

Plastics can be shaped and textured to enhance patient comfort when in contact with the skin or sensitive areas, reducing irritation or discomfort during prolonged use.

### 40. Reduced noise transmission:

Plastics can help reduce the transmission of noise or vibrations, ensuring a quieter environment during medical procedures or patient monitoring.

### 41. Compatibility with additive manufacturing:

Plastics can be effectively used in additive manufacturing techniques such as 3D printing, allowing for rapid prototyping and customization of medical devices.

### 42. Enhanced ergonomics:

Plastics can be molded or shaped to optimize ergonomic design, ensuring comfortable handling for healthcare professionals and ease of use for patients.

### 43. Reduced risk of breakage:

Plastics can withstand impact or bending without breaking, reducing the risk of device failure or injury in case of accidental mishandling.

### 44. Scalability:

Plastics offer scalability in production, allowing for large-scale manufacturing of medical devices to meet increasing demand and provide cost effective solutions.

### 45. Improved aesthetics:

Plastics can be molded into visually appealing designs, enhancing the aesthetics of medical devices and potentially improving patient acceptance and compliance.

### 46. Reduced risk of contamination transfer:

Plastics can be manufactured as single-use disposable devices, minimizing the risk of cross-contamination between patients and improving infection control practices.

### 47. Remote monitoring integration:

Plastics can be seamlessly integrated with electronics, facilitating the creation of wearable medical devices that



# SPE INDIA Medical Plastics Division

## 100 Benefits of Plastics in Medical Devices



- monitor vital signs and transmit data to healthcare providers for remote patient monitoring.
- 48. Reduced thermal expansion:**  
Plastics have low thermal expansion coefficients, maintaining dimensional stability and minimizing the risk of distortion or malfunction due to temperature changes.
  - 49. Enhanced wear resistance:**  
Plastics can be formulated to have improved wear resistance, ensuring the longevity and reliability of medical devices subjected to friction or repetitive motion.
  - 50. Compliance with biostability requirements:**  
Plastics used in medical devices can meet biostability requirements, remaining stable and inert when in contact with biological fluids or tissues.
  - 51. Soft Robotics Applications:**  
Plastics can be used in soft robotics components of medical devices, allowing for more flexible and adaptable devices for tasks like minimally invasive surgeries or patient assistance.
  - 52. Improved hygiene:**  
Plastics can be produced with smooth surfaces and minimal joints or crevices, reducing the risk of bacteria or debris accumulation and facilitating easy cleaning and disinfection.
  - 53. Integration of microfluidics:**  
Plastics can be used in microfluidic systems, allowing for precise manipulation and control of small volumes of fluids for diagnostic or analytical purposes.
  - 54. Enhanced precision:**  
Plastics can be molded with high precision, enabling the production of medical devices with tight tolerances, critical for accurate measurements or fine surgical procedures.
  - 55. Reduced interference with electromagnetic fields:**  
Plastics can be designed to have low electromagnetic interference properties, minimizing disruption to sensitive medical equipment or electronic devices.
  - 56. Compatibility with drug formulations:**  
Plastics can be selected based on their compatibility with specific drug formulations, ensuring stability, and preventing leaching or degradation of medications.
  - 57. Reduced risk of contamination in cleanroom environments:**  
Plastics can be manufactured under controlled conditions, minimizing particle generation and reducing the risk of contamination in cleanroom environments.
  - 58. Low water absorption:**  
Plastics can have low water absorption properties, ensuring dimensional stability and minimizing the risk of swelling or degradation when exposed to moisture or fluids.
  - 59. Improved chemical stability:**  
Plastics can be engineered to exhibit excellent chemical stability, resisting degradation or reactions when exposed to various chemicals or cleaning agents.
  - 60. Improved tactile feedback:**  
Plastics can be molded or textured to provide tactile feedback, enabling healthcare professionals to have better control and precision during procedures or interventions.
  - 61. Enhanced haptic properties:**  
Plastics can be formulated to provide specific haptic properties, such as softness, flexibility, or rigidity, enhancing the tactile experience and control during device use.
  - 62. Reduced friction with other materials:**  
Plastics can be engineered to have low friction coefficients when in contact with other materials, minimizing wear, and enabling smooth movements in medical devices.
  - 63. Reduced risk of thermal injury:**  
Plastics can be selected or designed to have high heat resistance, reducing the risk of thermal injury when medical devices come into contact with heat sources or hot surfaces.
  - 64. Improved chemical compatibility with drugs:**  
Plastics can be chosen based on their chemical compatibility with specific drugs or drug formulations, ensuring the stability and efficacy of medications when in contact with the device.
  - 65. Reduced risk of device migration:**  
Plastics can be designed to have surface features or textures that promote secure attachment or integration within the body, reducing the risk of device migration or dislodgment.
  - 66. Reduced manufacturing costs:**  
Plastics can be produced using cost-effective manufacturing processes, reducing overall production costs and making medical devices more affordable for healthcare providers and patients.
  - 67. Improved patient mobility:**  
Medical devices made from lightweight plastics enable enhanced patient mobility and comfort, allowing individuals to go about their daily activities with greater ease.
  - 68. Enhanced mechanical strength:**  
Plastics can be engineered to have high mechanical strength, enabling the development of robust medical devices that can withstand demanding applications or harsh environments.
  - 69. Improved dimensional stability:**  
Plastics can maintain their shape and dimensions over time, ensuring the accuracy and reliability of medical devices that require precise measurements or alignments.
  - 70. Reduced risk of allergic dermatitis:**  
Plastics can be selected or modified to be hypoallergenic, minimizing the risk of allergic dermatitis or skin reactions when in direct contact with the skin.
  - 71. Wearables and IoT Integration:**  
Plastics can be seamlessly integrated with Internet of Things (IoT) technologies, enabling real-time data collection and transmission in wearable medical devices.
  - 72. Microscale Devices:**  
Plastics can be microfabricated to create miniature medical devices, suitable for applications like microfluidics, minimally invasive procedures, or targeted drug delivery.
  - 73. Enhanced connectivity:**  
Plastics can be integrated with connectivity features, such as wireless communication or data transfer capabilities, enabling remote monitoring or seamless integration with healthcare systems.
  - 74. Nanotechnology Integration:**  
Plastics can incorporate nanomaterials to create medical devices with enhanced properties, such as improved drug delivery or increased sensitivity in diagnostic sensors.
  - 75. Reduced risk of cross-contamination in multi-use devices:**  
Plastics can be used to create disposable components or covers for multi-use medical devices, minimizing the risk of cross-contamination between patients.



# SPE INDIA Medical Plastics Division

## 100 Benefits of Plastics in Medical Devices



### 76. Enhanced precision in drug delivery:

Plastics can be molded into precise geometries, enabling accurate drug delivery or controlled release mechanisms, ensuring optimal therapeutic outcomes.

### 77. Reduced risk of infection:

Plastics can be manufactured with antimicrobial additives, reducing the risk of microbial colonization or infection associated with medical device use.

### 78. Compatibility with biological assays:

Plastics can be chosen based on their compatibility with biological assays or diagnostic tests, ensuring accurate and reliable results during laboratory analysis.

### 79. Enhanced chemical inertness:

Plastics can be engineered to have high chemical inertness, minimizing the risk of interactions or reactions with chemicals or biological substances used in medical procedures.

### 80. Reduced risk of needlestick injuries:

Plastics can be used in the development of safety-engineered medical devices, such as needle-free injection systems, reducing the risk of needlestick injuries and associated infections.

### 81. Improved heat dissipation:

Plastics can be designed with properties that facilitate heat dissipation, preventing overheating in medical devices with heat-generating components, such as electronics.

### 82. Reduced risk of device-induced trauma:

Plastics can be used in the production of medical devices with smooth or rounded edges, reducing the risk of tissue damage or trauma during device insertion or use.

### 83. Reduced risk of device rejection:

Plastics can be engineered to have low immunogenicity, reducing the risk of device rejection or immune responses when used in implantable medical devices.

### 84. Enhanced stability in harsh environments:

Plastics can withstand exposure to harsh environmental conditions, such as extreme temperatures, humidity, or chemical exposure, maintaining device stability and functionality.

### 85. Compatibility with telemedicine:

Plastics can be integrated with telemedicine technologies, facilitating remote patient monitoring, data transmission, or virtual consultations for improved healthcare delivery.

### 86. Improved patient compliance:

Plastics can be used to create user-friendly and aesthetically pleasing medical devices, enhancing patient acceptance and compliance with treatment regimens or device usage.

### 87. Reduced risk of cross-reactivity:

Plastics can be selected to minimize cross-reactivity with common allergens or sensitizing agents, reducing the risk of allergic reactions or hypersensitivity in patients.

### 88. Enhanced visibility in low-light conditions:

Plastics can be manufactured with properties that enhance visibility in low-light conditions, allowing for better visualization of medical devices during procedures or surgeries.

### 89. Reduced risk of contamination during storage or transport:

Plastics can be used to create sterile and sealed packaging for medical devices, protecting them from contamination during storage or transportation.

### 90. Improved bioabsorbability:

Some plastics used in Medical devices are bioabsorbable, gradually breaking down and being absorbed by the body over time, eliminating the need for device removal.

### 91. Compatibility with minimally invasive procedures:

Plastics can be used in the development of minimally invasive medical devices, such as endoscopes or laparoscopic instruments, enabling less invasive procedures and faster patient recovery.

### 92. Aesthetic Customization:

Plastics can be molded into aesthetically pleasing designs, which is particularly relevant for external medical devices, enhancing patient self-esteem and acceptance..

### 93. Enhanced visibility in imaging modalities:

Plastics can be formulated to be radiolucent or MRI-compatible, ensuring clear visibility and minimal interference in imaging modalities used for diagnostic or monitoring purposes.

### 94. Reduced risk of thermal damage to surrounding tissues:

Plastics can have low thermal conductivity, minimizing heat transfer and reducing the risk of thermal damage to surrounding tissues during energy-based medical procedures.

### 95. Compatibility with robotic-assisted surgeries:

Plastics can be used in the development of medical devices compatible with robotic-assisted surgeries, enabling precise movements and accurate surgical interventions.

### 96. Reduced risk of contamination from medical device components:

Plastics can be manufactured with tight tolerances, ensuring proper fitting and reducing the risk of contamination from loose or ill-fitting device components.

### 97. Enhanced flexibility for catheter-based procedures:

Plastics can be used in the production of flexible catheters, enabling smooth navigation through blood vessels or other anatomical structures during procedures.

### 98. Reduced risk of material fatigue:

Plastics can be engineered to have high fatigue resistance, ensuring the longevity and reliability of medical devices subjected to repetitive stress or motion.

### 99. Compatibility with biological scaffolds:

Plastics can be used in the development of scaffolds for tissue engineering or regenerative medicine, providing a biocompatible support structure for tissue growth or repair.

### 100. Improved device tracking and identification:

Plastics can be easily marked or labeled with identification codes or tracking information, facilitating device traceability, inventory management, and patient safety.



# New Technology and Next Gen Design Vascular Interventional Medical Device

**Ravi Shankar Srivastava**

Managing Director  
Conquest Medtech LLP, Mumbai, India.

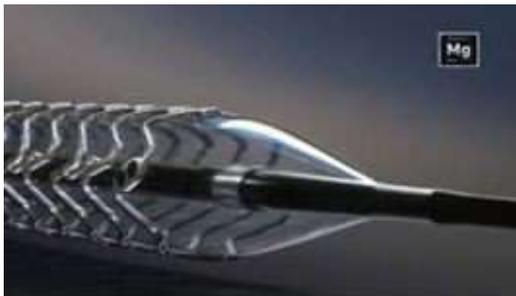
## 5th Generation Innovation

### Bio absorbable Stent

#### Why Absorbable Stents?

Vessel scaffolding is necessary only for a certain, limited time, than the permanent implant has no known advantage

- Short duration of anti platelet therapy post stenting
- **Avoid chronic** inflammatory processes
- **Problem of re-intervention with** traditional techniques
- **Ability of the vessel to perform** positive remodeling and natural vasomotion achieved
- Preferred choice for young population
- Patency of the original vasculature is maintained
- **Peripheral application: no longer crushing issue after absorption**
- CT and MR – (**follow up**) compatibility

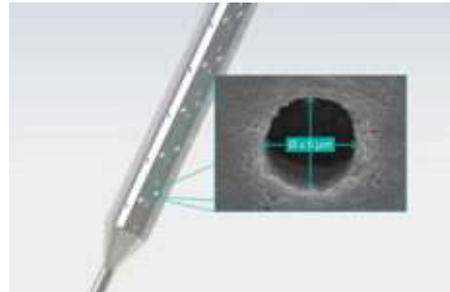


- Superior radial strength of 9 to 12 months.
- Earlier devices lacked the anti proliferative drug.
- Bio reabsorb able – “leave nothing behind”
- MRI compatibility
- Degradation time is adjustable by customize coating.
- Improved break elongation.
- End products(corrosion) : inorganic salts.
- Reduced strut thickness, small crossing profile, higher lumen patency.

## Futuristic Innovation in Drug Eluting Balloon/Drug Delivery Balloon

- DEB can have different types of drug carriers like Paclitaxel, sirolimus, etc
- Release of the drug can be customized
- Nanotechnology can be effective for coating
- DEB have various application in small lesions, restenosis lesions, diffused disease

- Micro drilled DDB an alternative to DEB can be effective in less drug loss
- DDB ensures localized intraluminal drug delivery
- DDB can release drug multiple time by repeat dilation
- DDB can treat multiple lesions consecutively
- Delivery dose depends on duration of dilation in DDB
- Various drugs can be delivered at various lesions depending on the morphology



## TAVI (Trans Aortic Valve Implantation) Heart Valve Indian Innovation

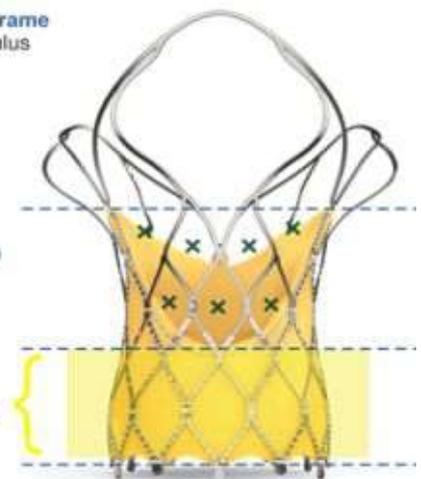
**Self-Expandable Nitinol Frame**  
Conformable to native annulus

**Three Tentacle Design**  
Less metal at outflow

**Large Frame Cells (≥15F)**  
Facilitates easy access to the coronary arteries

**Extended Sealing Skirt**  
Mitigates paravalvular leak

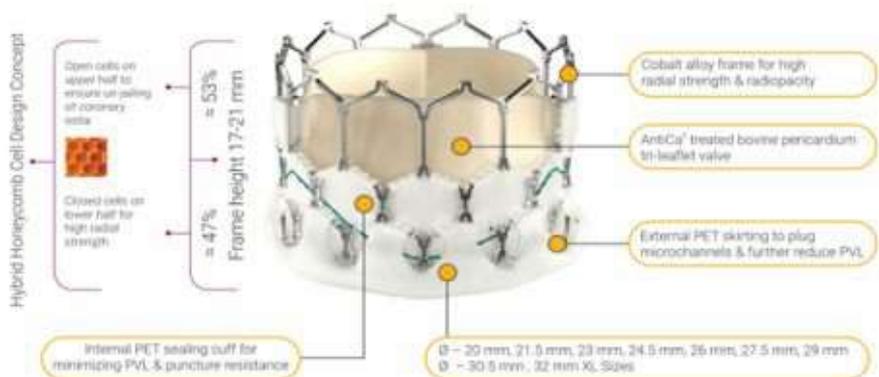
**Non-Flared Inflow Part**  
Reduces conduction abnormality



Each 'X' represents a single large cell

HYDRA (CE1434) Trans Catheter Aortic Valve has been developed by Sahajanand Medical Technologies, India

## Myval THV: Designed for Precision in Outcomes

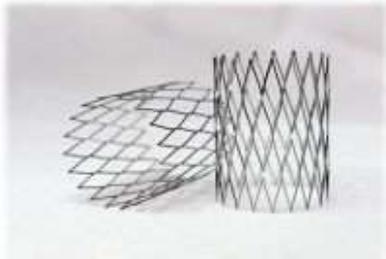


Myval THV has been indigenously developed by Meril Life Sciences Pvt. Ltd.

ANZCA, NATA's primary accreditation technology approval  
All Myval THV sizes are CE approved

### New Innovations in Heart Valves (TAVI)

- **Frame Manufacturing is a Matter Close to Our Hearts**
- Transcatheter Aortic Valve Implantation (TAVI), also known as percutaneous aortic valve replacement (PAVR), is now the standard for heart valve surgeries. Since the development of this revolutionary technique, MeKo has been manufacturing the metallic frames of the valves – with the highest quality and unparalleled fatigue life.
- Highest Precision "Made in Germany"
- ISO 13485 certified quality management system



On Balloon expandable heart valve frame we can perform bio Glycocalix coating which is a perfect imitation (biomimicry) of the glycocalix molecule. The vessel wall and blood (cells) recognize it as a natural part of the body



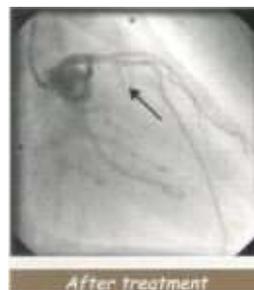
This picture shows the endothelial membrane with its external layer of glycocalix

### New unique ASA (Alcohol Septal Ablation) balloon Catheter for Hypertrophic Cardiomyopathy

- Large diameter coiled kink-resistant inner lumen for easy injections of contrast media and alcohol.
- Small size semi-compliant balloon for excellent matching, anchoring and sealing of the septal branches.

#### Product specifications

- SLC coated catheter with polyimide shaft
- Usable length 140 cm
- Exit markers at 90 and 100 cm
- 2.8 French flexible tip section
- Crossing profile 0.020"-0.040" (depending on)
- Balloon length 10 mm
- One proximal radiopaque marker
- Tack-seal near balloon
- Compatible with a 0.014" guidewire
- Recommended guiding catheter 6 French
- Nominal pressure 6 Atm
- Rated burst pressure 10 Atm



The represented data is from the principal company website. Confidential and for internal circulation only.



# Introduction To Chemical Characterization of Medical Devices

## Dr. T S Kumaravel

Founder Chairman  
GLR Laboratories, UK

## Dr. R M Balaje, Dr. S S Murugan, Dr. T S Kumaravel

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### Introduction

Chemical characterization is a critical step in the biological evaluation of medical devices.

ISO 10993-18:2020, part of the ISO 10993 series, provides a framework for identifying and quantifying the chemical constituents of a medical device. This process is essential for assessing potential biological risks and ensuring patient safety. This characterization helps to understand the material composition and predict potential biological effects, forming the basis for further biological testing and risk assessment.

### Preliminary Material Assessment

The raw materials, design and components of medical device together with its manufacturing processes are need to be assessed. This assessment should include potential contaminants, degradants, processing aids and additives which could be introduced by the manufacturing and packaging process. The list of potential chemicals of concern, based on the device's materials and intended use are identified.

For an effective material assessment, medical device manufacturers should provide qualitative and quantitative compositional information about the device raw materials/ingredients. Also, the quantitative information about any additional processing additives used, possible impurities, residual monomers should be provided. This information will be useful in preparing a hazard-based risk assessment (Kumaravel et al, 2022). In the absence of such material information, a comprehensive chemical testing (e.g. compositional, extractables, or leachables testing) need to be performed.

### Extractable/Leachable Study

Extractables are chemicals that can be extracted from a device under exaggerated/exhaustive extraction conditions, while leachables are chemicals that can migrate into the body under normal clinical use conditions. The extractable study should be designed using appropriate solvents and extraction conditions to simulate exaggerated conditions or clinical use depending on the category of body contact and duration of clinical exposure. Following device extraction, the extracts are need to be analyzed by various chromatographic and spectroscopic techniques for the qualitative and quantitative estimation of organic compounds and elemental impurities/metals. The extractable or leachable

study should be designed with consideration for the toxicological risk assessment that will be performed on the extractable/leachable compounds. Therefore, consulting a toxicologist during the study design phase is advisable to ensure the generation of specific data needed to facilitate exposure-based risk assessment.

### Analytical Techniques

ISO 10993-18 emphasizes the use of robust analytical methods for chemical characterization. The commonly used techniques include (i) Gas Chromatography (GC): Suitable for volatile and semi-volatile compounds, (ii) Liquid Chromatography (LC): Ideal for non-volatile and thermally labile compounds, (iii) Inductively Coupled Plasma Spectroscopy (ICP): Provides information on elemental impurities and (iv) Fourier Transform Infrared Spectroscopy (FTIR): Useful for identifying organic compounds based on their functional groups.

### Significance of Chemical Characterization Data

- Chemical characterization results are integral to the overall biological evaluation of a medical device. The identified chemicals are assessed for their potential biological effects, including toxicity, carcinogenicity, and sensitization. This assessment helps to determine the need for additional testing and informs the overall risk management process.
- Chemical characterization data are utilized in risk assessment to evaluate the toxicological equivalency of a proposed material compared to an already clinically established material for similar clinical exposure.
- To generate chemical fingerprint of existing medical device and to compare it with the future device variant, if the manufacturers change their material suppliers.
- Required to better design an integrated medical system using different types raw material in a single device.
- Helps in understanding, how various material interactions will ultimately affect the patients.
- It Provide insights into predicting the biocompatibility outcomes.
- It can suggest possible causes of adverse biocompatibility outcomes & mitigation opportunities.

### Toxicological Risk Assessment

Toxicological risk assessment is a critical process in the

biological evaluation of medical devices, ensuring the biological safety of medical devices for their intended use. ISO 10993-17:2023 provides guidance on evaluation of potential health risks for the extractable/leachable substances released from medical devices by establishing scientifically valid allowable limits (maximum acceptable concentration of a leachable substance that poses no significant health risk to the patient). The results of toxicological risk assessment inform the overall risk management process for the medical device. Manufacturers should integrate these findings into their risk management plans, ensuring continuous evaluation and mitigation of potential risks throughout the device's lifecycle, thus protecting patient health.

Toxicological risk assessment of leachables from medical devices as per ISO 10993-17:2023 involves a systematic evaluation to ensure patient safety. The process begins with the identification of leachables, followed by a detailed hazard identification to determine potential toxic effects. Dose-response assessments establish the relationship between exposure levels and adverse effects, while exposure assessments estimate the actual levels of leachables patients might encounter during device use. Risk characterization then compares these exposure levels to toxicological thresholds, culminating in the derivation of allowable limits for leachables. This approach integrates scientific data and regulatory standards to ensure that medical devices do not pose significant health risks, supporting the overall biological safety evaluation and risk management efforts.

- 1. Identification of Leachables:** Identify the leachable compounds that may leach from the device under clinical use conditions.
- 2. Hazard Identification:** Determination of potential toxicological hazards associated with each identified leachable by reviewing the existing toxicological data from scientific literature, databases, and regulatory sources (Balaje et al,2023)
- 3. Derivation of Allowable Limits:** Establishing a relationship between the dose of the leachable, and the observed toxicological effect and thereby, establishing no-observed-adverse-effect levels (NOAELs) and relevant toxicological thresholds (TI).
- 4. Exposure Assessment:** Estimation of potential exposure (EEDmax) of patients to leachables during the device's use by considering factors such as duration of exposure, patient population, and clinical use.
- 5. Risk Characterization:** Comparison of estimated exposure levels to the established toxicological thresholds and assessment of the level of risk by calculating margin of safety. Margin of safety can be helpful in addressing biocompatibility endpoints like genotoxicity, carcinogenicity, systemic toxicity and reproductive or developmental toxicity.

### Supplementary Methods for assessing toxicity

- a) Quantitative Structure-Activity Relationship (QSAR):** Predicts toxicological properties of chemicals with limited toxicological data, based on chemical structure.
- b) Threshold of Toxicological Concern (TTC):** Establishes exposure thresholds for chemicals with limited toxicological data.
- c) In vitro and In vivo Testing:** Provides experimental data on the toxicological effects of leachables.

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### FAST FACTS

**Ethylene oxide** is the most commonly used method to sterilize medical devices manufacturers and contract sterilizers worldwide. While some novel technologies hold promise, innovative alternative sterilization methods are still in early phases of research and development.

## SEEKING TO ACQUIRE

fully operational medical device manufacturing facility with **Class A and Class B** licenses for medical devices.

### PREFERRED LOCATION GUJARAT

### CONTACT ON

+91 94275 65957  
contact@alishsinojiya.com





# Regulatory Issues In Supply Chain & Contract Manufacturing (out sourcing) Of Medical Devices

**Sanjay Shah**  
Unikal Consultant

Medical devices are unique in their definition and it has large varieties and variants covered under the term. Again Medical devices are classified under different categories. The classification is mainly depended on its usage, its design and software used, risk involved in their intended application and based on the usability (“Usability”- medical device is the characteristics of the User Interface that facilitate Use, to make it easier for the users to perceive the information presented by the User Interface, to understand and make a decision based on that information).

Thus regulations covering medical devices are also have many requirements to be complied with. Thus all aspects of development, manufacture, sales and post sales support are complex processes. Quality aspect pre- & post manufacturing is a very complex in their nature based on their application and usage.

Looking at the complexity of manufacturing of medical devices outsourcing or contract manufacturing becomes an accepted process.

There are companies which are experts at designing, expert at component manufacturing of various types like moulding, companies which only assemble different components and companies which carry out sterilization process.

The manufacturer, whose name appears on the label is ultimately responsible for the ownership of Device.

Thus Establishments that are involved in the production and distribution of medical devices intended for commercial distribution are required to list the devices and the activities performed on those devices at that establishment.

The Medical Device Regulation (MDR) has placed more focus on the supply chain of medical device manufacturers that market their devices in the European Union.

Therefore, suppliers in the Medical Device industry, should have a good understanding of needs and requirements including need to understand their role as per MDR & maintain their Quality management System.

The suppliers of critical input materials and / or component manufacturers have to have their share of responsibilities. This is because finally components which go in to final assembly of Medical Devices will be critical for its success or failure. Failure in medical device usage can be very serious.

Based on the classification and risk based evaluation of medical device decides required controls and quality management systems requirements at the supplier level.

They need to follow guidelines of QMS for Medical Devices, viz.

ISO 13485. Following are some of the important clauses and requirements as per QMS Standard:

4.1.5 When the organization chooses to outsource any process that affects product conformity to requirements, it shall monitor and ensure control over such processes. The organization shall retain responsibility of conformity to this International Standard and to customer and applicable regulatory requirements for outsourced processes. The controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with 7.4. The controls shall include written quality agreements.

These and other clauses very clearly state the types of the controls required on the suppliers. Periodical audit from the manufacturer is a must. As per MDR guidelines, even notified body is directed to audit suppliers in a predefined manner based on the device class and criticality of supplier and service provider (e.g. device sterilization)

The supplier needs to be clear about what is the design and specifications of the components. Suppliers need to get critical testing done and keep the records of production batches, testing records and maintenance of related equipment calibrations.

These is putting lots of compliance requirements on the entire supply chain. The implementation of the same is mandated on the manufacturer and thus puts additional responsibility on the device manufacturer. They in turn are bound to insist on similar compliance responsibility on their suppliers.

A detailed line of requirements must be the part of agreement between the two.

Supply chain and purchase department of the manufacturer needs to have enough qualified people to oversee the activity.

The purchasing process requirements as per QMS is extracted here as a sample and example.

### 7.4.1 Purchasing process

The organization shall document procedures (see 4.2.4) to ensure that purchased product conforms to specified purchasing information.

The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be:

- based on the supplier’s ability to provide product that meets the organization’s requirements;
- based on the performance of the supplier;
- based on the effect of the purchased product on the quality of the medical device;
- proportionate to the risk associated with the medical device.

What information need to be shared between manufacturer and their supplier is summarized below: (Do note this is not exhaustive)

- product specifications;
- requirements for product acceptance, procedures, processes and equipment;
- requirements for qualification of supplier personnel;
- quality management system requirements.

Purchasing information shall include, as applicable, a written agreement.

Records of the components production shall include details of traceability and complete details of production process, their adherence to the SOPs.

It is very clear that supplier cannot make changes in the design, specifications or composition of the components without prior permission from the manufacturer.

This is very critical because these changes can have impact on the functioning, performance and risk of usage of the Medical Device.

To get assurance of the compliance, Manufacturer who buys components need to carry out;

Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product.

Thus component manufacturers have to be communicated and should be aware of:

Specifications of components, testing methods and writing, maintaining and preserving reports.

Their machinery, testing equipment and measurement equipment needs to undergo planned maintenance and Calibrations.

All equipment needs to have completed DQ, IQ, OQ & PQ and records of the same are maintained.

Process validations needs to be carried out in collaboration with the manufacturer's requirements.

Component manufacturer should have Awareness of Medical Device a needs.

They should be aware of the risk based manufacturing processes along with the Device's design and development knowledge for compliance

During quality control, a details specifications, test methods and Sample size to be tested has to be understood based on the manufacture's requirements at the component stage.

They need to carry out validation of manufacturing processes based on the design documents.

Component manufacturers need to demonstrate Responsibility for confidentiality of methods and documentation received from the manufacturer.

Traceability of production process, materials used in the components needs to be maintained.

They need to carry out internal and external (third party) audits, maintain audit trail Also plant compliant like Pollution control system and other legal requirement compliance Aware of risk management relating to the component.

The component suppliers need to understand the requirements of CAPA and support in handling customer complaints. This is to assist the manufacture in case of complaints or device failure.

After going through above stringent sounding but absolutely necessary requirements and controls on the component manufacturers, one might wonder why not have every aspect as in-house for the Medical Device manufacturers.

The component manufacture or out sourcing of manufacturing in medical device industry is usually accepted and to an extent necessary.

A few justifications on the requirement of contract manufacturing (outsourcing production) or component manufacturing: including facility costs or a reduction in labour costs.

Why Consider Outsourcing to a Contract Manufacturer?

Manufacturing may not be a core competency of an organization. The device requires high development and clinical costs, which may limit the resources required to engage in high quality and high productivity manufacturing.

Organization's financial objectives result in the consideration of reducing company overhead, Contract manufacturers are hired to build small subassemblies (many build complete assemblies) that then will be sent to the client for final assembly into a larger unit.

**It can reduce costs and provide access to expertise that is not available in house.**

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**- Henry Ford**



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## Mexico Medical Devices Market

### Mr. Amit Dave

M. Pharm, MBA  
Former CEO – Brazil operations/ Vice President Export -  
Zydus Cadila Claris Lifesciences

### Country Profile

Mexico is on the southern side of North America and shares a large border with the USA. After Brazil and Argentina, Mexico is the third largest country in Latin America. Its population is 13.3 cr (2024 estimate) which is much less than that of Brazil. But the medical devices market size is close to 16 bn USD (Brazil's market size is 12 bn) and that makes the Mexico market equally interesting. The official language is Spanish and the currency is Mexican Peso.

More than 60% population of Mexico is less than 44 years of age, with the median age of 29 years. The USA is the largest import partner, with more than 40% of imports of the country coming from the USA, and the second largest partner is China with a 19% import contribution. On the other side, almost 80% export of Mexico is to the USA. The market and economy of Mexico is strongly tied to that of the USA. Foreign remittances from Mexicans abroad (mainly in the USA) contribute billions of dollars to the Mexican economy each year.

In the mid-1990s the North American Free Trade Agreement (NAFTA) created a free-trade zone between Mexico, the United States, and Canada. Under Trump's administration in 2018, Mexico, the United States, and Canada signed the United States–Mexico–Canada Agreement (USMCA), which preserved much of NAFTA but also introduced several significant changes to the accord.

### Regulatory Framework and Product Classification

COFEPRIS (Comisión Federal para la Protección contra Riesgos Sanitarios), under the Mexican Ministry of Health (Secretaría de Salud) is the registration authority for medical devices in Mexico. Hard copies (documents) rather than soft copies are to be submitted here. Though the official language is Spanish, technical documents in English are also workable. The process suggested for registration is as follows-

Step 1 : Determine the classification of your device as per the Mexico classification rules.



Step 2 : Appoint a local (Mexican) party (a distributor) for registrations and liaise with COFEPRIS.

Step 3 : Prepare proof of an audited quality system (necessary for registration application).

Step 4 : A dossier and application form for COFEPRIS submission are to be prepared.

Step 5 : Deposit the registration fee.

The classification of devices follows Class I, II and III. The basis for classification is somewhat ambiguous, it must be noted. The broad outline of classification is based on the degree of risk, like many countries. Class I Medical Devices are associated with the lowest risk, while Class III Medical Devices are associated with the highest risk. For the products of other than Class I, it takes 10 to 12 months for approvals.

### Mexico Medical Devices Market

Mexico's medical device market was estimated to be approximately \$15.6 billion (for the year 2023) with a projected growth rate of 8.3%. Cardiology Devices have the largest market share increasing adoption of digital health technologies, telemedicine and remote patient monitoring devices is growing rapidly, along with wearable devices. It is important to note that many American companies have made manufacturing units in Mexico and thereby, export contribution of this sector is also high, along with American competition.

Baja California, bordering the United

### Mexico Highlights

- Very large market for medical devices
- Regulatory Framework simple, but unexpected delays expected
- Huge import of medical devices
- Competition from the US companies

States (close to San Diego) has become a major manufacturing hub for medical devices, and is home to the Medical Device Cluster, with over 70 companies accounting for a substantial portion of the country's exports. There are 6 other clusters for medical device manufacturing. Top medical device companies in Mexico include Medtronic, Johnson & Johnson, Thermo Fisher Scientific, Stryker, Becton, Dickinson and Company (BD), Siemens Healthineers, and Cardinal Health. Contract manufacturing for devices with world-class facilities has also flourished here. Mexico is the seventh largest medical device manufacturing country in the world. It is important to note here that Mexico is the third largest importing country also for devices and the readers should see the opportunity from this perspective.

Many companies in Mexico claim that they can achieve lower costs to the market than the Asian companies, which can be a competitive advantage. Immediate access to the US market and strong R&D infrastructure can also help some ambitious Indian players.

### Opportunities and Challenges

This is a market with a good size and an impressive growth rate, with good realizations, with a possible access to the US market. Though the regulatory regimen looks simple and is in line with similar advanced countries, there can be uncontrolled delays in approval and the process can be delayed by months. This is a challenge. Also, one more challenge would be to give higher-end products as this is an advanced market. Along the same lines, competition from US products can also be challenging. The future possibility of local manufacturing subject to economic and technical feasibility may be worth exploring for other LATAM markets.



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- |                              |  |
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| <b>ISO 14971:2019</b>        | : Medical devices — Application of risk management to medical devices                    |
| <b>ISO/TR 20416:2020</b>     | : Medical devices — Post-market surveillance for manufacturers                           |
| <b>IEC 62304:2006</b>        | : Medical device software — Software life cycle processes                                |
| <b>EU MDR</b>                | : European Union Medical Device Regulation   |
| <b>QMSR</b>                  | : Quality Management System Regulation   |
| <b>(As release by USFDA)</b> |  |
| <b>MDSAP</b>                 | : Medical Device Single Audit Program  |
| <b>Schedule – M</b>          | : As per drugs and cosmetics act 2024 (Good Manufacturing Practices for pharmaceuticals) |
| <b>SEDEX</b>                 | : Supplier Ethical Data Exchange   |



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## Exclude Medical Devices From The List Of India-EU Free Trade Agreement (FTA) Items: AiMeD

- Imports of these items in India jumped 68% in the last four years
- India already dependent on imports of medical devices to the tune of 70% presently
- Whenever India has signed any FTA with another country, the imports of medical devices into India have increased

New Delhi, 24 Sep 2024: In view of the steep growth in imports of medical devices from Europe and other countries into India, the domestic manufacturers of these devices have demanded the exclusion of medical equipment and consumables from the list of EU Free Trade Agreement (FTA) items.

Amidst the ongoing India-EU FTA talks, in a letter written to the Commerce Ministry, the Association of Indian Medical Device Industry (AiMeD) has highlighted that the imports of these items in India has grown at a staggering rate of 68% in the last four years, making India dependent on imports to the tune of 70% currently. At a time when India's existing import duty on medical devices is already very low (0.0%-7.5%), bolstering imports further by including these medical items in the EU-FTA list would not only jeopardize the medical security of India but also prove to be highly detrimental to the domestic manufacturing industry, according to Mr Rajiv Nath, Forum Coordinator, AiMeD.

Whenever India has signed any FTA with another country, the imports of medical devices into India have only grown. India signed the Japan-India Comprehensive Economic Partnership Agreement (JICEPA) but the imports of medical equipment from Japan has risen from Rs 1826 crore in FY20 to Rs 3085 crore in FY24, a jump of 19%. Similarly, India inked India-Singapore Comprehensive Economic Cooperation Agreement (ISCECA) but the imports from Singapore have jumped from Rs 4294 crore in FY20 to Rs 6779 crore in FY24.

Germany and Netherlands, both EU countries, are already among the top five exporters of medical devices into India. "EU has many non-tariff barriers for Indian imports into any EU nation. We need a Tit-for-Tat policy from India's side. Indian manufacturers require CE Certification to sell to EU nations which is not only an expensive affair but also leads to a lot of time wasted in getting the certification - approximately 2 years. EU nations get our factories inspected rigorously before buying from here. We need a similar policy from India where-inspection of EU factories and verification of compliance to Indian Medical Device

Rules (MDR) and also of Domestic Content in EU factories is done by Indian regulators," said Mr Nath in AiMeD's letter to the Commerce Ministry.

AiMeD has also highlighted that the regulatory system for medical devices in the EU permits organizations to label themselves as a 'Legal Manufacturer' even if they are not making the product themselves. This was done to allow EU regulators to make Market Authorization Holder to be responsible and accountable from the patient safety perspective but this facility has been abused and lead to pseudo manufacturing to thrive in EU as Country of Origin is not insisted upon on the labeling of medical devices in Europe & UK, unlike the case of USA & India, which seek labeling of 'Country of Origin' on medical items. There's a huge risk of 3rd country exports to be routed via EU to India under this legal manufacturing route whereby a marketing company can pass itself off as a legal manufacturer.

The Indian medical device manufacturing industry has been given assurance in past for UK-India FTA that 'Legal Manufacturer' labeled packages will not enjoy 'ZERO Duty' FTA benefits if the manufacturer/ exporter is not an actual manufacturer and not able to prove that he assembles and manufacture the medical device in the UK with at least 40% value addition. AiMeD has sought to know how this assurance will be enforced.

"When there is inspection is done by Bureau of Indian Standards (BIS) for items like steel and plastics when imports are involved, then why not make it mandatory for factories if Medical Devices in foreign countries to be inspected by BIS and CDSCO in case of medical devices which are far more crucial than simple plastic items," said Mr Nath.

China, Singapore, Malaysia, Japan, South Korea, Thailand, Argentina, Vietnam, Indonesia, Philippines, New Zealand, etc. have gained much more than India after FTAs were signed by Indians with them.

## Govt Considers Random Testing Of Imported Medical Devices

### Synopsis

The government is planning to enhance the quality monitoring of imported medical devices by implementing a risk-based approach. This will involve random sampling for quality tests and full cargo testing for critical diagnostic kits. A guidance document has been issued for port officers to assist in this process, emphasizing the importance of public health safety.

**The government is contemplating monitoring the quality of medical devices entering the country by mandating a risk-**

**based approach wherein random samples will be picked up and tested for quality, while in case of critical diagnostic kits, the whole cargo will be tested.**

**The government has come out with a document to provide guidance to port officers to take appropriate decisions for monitoring quality at the port of import based on a risk-based approach.**

*( The Economic Times, September 24 , 2024 )*



## India To Offer 20 Per Cent Capital Subsidy For Domestic Production Of Medtech Components

India is known as the pharmacy of the world because of its generic medicines and low-cost vaccines. It has the highest number of United States Food and Drug Administration (USFDA) compliant Pharma plants outside of the USA. However, in the medical devices sector, the country remains heavily dependent on imports with nearly 70 per cent of the products being sourced from other countries.

The govt is planning to launch a new scheme to incentivise the

medtech or medical technology industry to manufacture components for digital X-ray, CT scan and MRI machines in the country.

Currently, most such components are imported leading to high cost of the devices and, therefore, the cost of medical imaging.

(<https://manufacturing.economictimes.indiatimes.com>  
Aug. 30, 2024)

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## Make In India' In Focus, AIIMS To Set Up Centre For Medical Devices With Osaka University

AIIMS and Osaka University have been working on the project for two years. In the last two years, several AIIMS faculty members visited Osaka University in Japan for training purposes.

With the central government's 'Make in India' initiative at the heart of the project, the All India Institute Of Medical Sciences (AIIMS) in Delhi has collaborated with Osaka University in Japan to set up a centre in Haryana's Jhajjar where medical devices will be developed.

The National Centre for Medical Device Development, Validation and Skill Training is expected to provide a platform for Indian surgeons, physicians, and biomedical engineers to conceptualise, design, develop, and test medical device prototypes, said officials. It will give a boost to the preparation of designs and technologies as per the requirements of the doctors, and testing on animals and human cadavers.

Dr Hemanga K Bhattacharjee, Professor of Surgical Disciplines at AIIMS, said the move is significant because nearly 70% of the devices and equipment are imported from developed countries despite the 'Make in India' policy in place.

AIIMS and Osaka University have been working on the project for two years. In the last two years, several AIIMS faculty members visited Osaka University in Japan for training purposes. Now the AIIMS administration has sought a budget of Rs 300 crore from the Union Health Ministry. "The land has been finalised and the government has also given an in-principal approval for the budget," said Dr Bhattacharjee.

On Monday, a delegation of doctors led by Dr Bhattacharjee,

along with specialists from other departments, scientists and technical officers from AIIMS, held a meeting with the Japanese delegation to learn more about cutting-edge technological research and hands-on experience on prototype conceptualisation, computer-assisted designing, 3D printing for rapid prototype and subsequent manufacturing experience. "Now we have the Japanese delegation here to discuss and teach us how the centre will be established. All the AIIMS faculty members will be a part of this programme," said Dr Bhattacharjee.

The Japanese delegation led by Dr Kiyokazu Nakajima, Professor in the Department of Next Generation Endoscopic Intervention at Osaka University Graduate School of Medicine, on Monday held discussions on technical aspects and proposals for creating the state-of-the-art, publicly-funded research centre for medical device development, validation and skill training. The Japanese doctors also visited the proposed site for the centre at AIIMS Delhi's Jhajjar campus.

Dr Bhattacharjee underlined, "We have had an MoU (memorandum of understanding) with the Osaka University for 10 years for research but now we are taking it forward and will move towards the infrastructure and development of medical devices under the Make in India scheme."

<https://indianexpress.com/article/cities/delhi/make-in-india-in-focus-aiims-to-set-up-centre-for-medical-devices-with-osaka-university-9536851/>  
August 28, 2024

## Andhra Pradesh MedTech Zone ( AMTZ ) Launches India's First Indigenously Developed Mpox RT-PCR Kit

Developed in partnership with Transasia Diagnostics Private Limited, the kit has achieved validation from Indian Council for Medical Research and received emergency authorisation from Central Drugs Standard Control Organisation

The Visakhapatnam-based Andhra Pradesh MedTech Zone (AMTZ) on August 24 (Saturday) announced a groundbreaking development in diagnostic technology by launching 'ErbaMDx

MonkeyPox RT-PCR Kit'.

The announcement comes at a time when the Union Government has been issuing a series of alerts in the wake of growing concerns about the spread of Mpox, (formerly known as monkeypox) virus, while assuring people that there is no need to worry as no severe case has been detected so far.

## Kerala's Advances In Biomedical Device Development Sector In Spotlight At BioConnect 2.0

Kerala's skilled workforce, robust healthcare system, and world-class research institutions a boon for State to become a leader in sector, say industry leaders.

Kerala's recent advances in the biomedical device development sector came into the spotlight on the second day of BioConnect 2.0 life sciences conference hosted by the Kerala Life Sciences Industries Park (KLIP) on Saturday, September 28. Industry leaders expressed confidence that the State could soon become a national leader in the sector with its skilled workforce, robust healthcare system, and world-class research institutions.

Usha Thekkedath, Programme Director at UCSF Surgical Innovations in the US, Santhosh Kumar, CEO of Harrison's Malayalam Limited, Thomas John, MD of Agappe Diagnostics, and Pius Varughese, COO of Vinvish Technologies spoke in a session titled 'Enhancing Medical Device Industry Ecosystem'.

Mr. Santhosh highlighted Kerala's natural advantages, including its well-educated workforce and availability of natural rubber,

which could help significantly reduce production costs for medical devices. "A product that costs ₹5,000 using synthetic rubber can be produced for just ₹300 with natural rubber," he said, suggesting that local production could offer a competitive edge.

Currently, 70% of India's medical devices are imported, with only 33% manufactured domestically. Of that share, 20% is produced in Kerala. Thomas John of Agappe Diagnostics stressed the importance of government support in enabling Kerala to become a global player. Pius Varughese pointed to a significant gap in the ecosystem in the lack of semiconductor manufacturing companies, which are crucial for advanced medical devices. He called for efforts to attract such firms to Kerala and emphasised the need for more testing laboratories to validate and certify new products.

The panel also discussed Kerala's strategic advantages in infrastructure, with facilities like Vizhinjam International Seaport,

## Industry News

Thiruvananthapuram International Airport, and technology hubs such as Technopark and Bio 360 Life Science Park providing strong support for the biomedical industry. Mr. Varughese said that Thiruvananthapuram is an ideal location for developing a biomedical cluster, given the presence of key institutions like Isro, BrahMos, and the Medical Technology Park.

The State has established the Kerala Medical Technology Consortium, which has already brought together 85 companies and 357 startups, generating annual revenues of ₹8,722 crore. The sector is expected to grow exponentially, with projections of ₹16,600 crore in revenue by 2027, 300 companies, and 3,500 startups by 2032, potentially reaching ₹34,750 crore in revenue.

( <https://www.thehindu.com> , September 28, 2024 )

### FAST FACTS

#### How COVID-19 changed medical device clinical trials forever

Four takeaways from the pivot to remote monitoring of trials are:

1. Virtual monitoring has not hurt quality or safety
2. Remote trial monitoring has decreased trial costs
3. The adoption of various technologies has increased
4. Remote monitoring and hybrid trials are here to stay

( courtesy :

<https://www.medicaldesignandoutsourcing.com> )

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## Bry-Air Enhances Medical Plastics: The Right Choice for Resin Drying

(Courtesy: Bry-Air (Asia) Pvt. Ltd.)



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**Nano Dryer:** Tailored for smaller-scale operations, the Nano Dryer offers precise drying for engineered plastics with throughputs of 6-12 kg/hr. Available in 15 and 25 CMH models, it is designed to mount directly on hoppers, saving valuable floor space. Like the Wonder Dryer, the Nano Dryer operates at a dew point of -40°C, ensuring high-quality output. Its compact design, zero footprint, and huge power savings (up to 50%) make it an excellent choice for micro and miniature medical component processing units.

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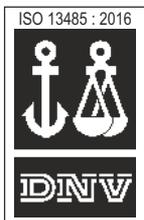
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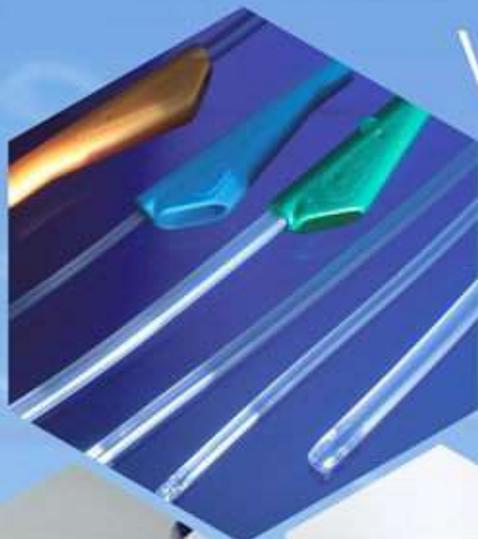
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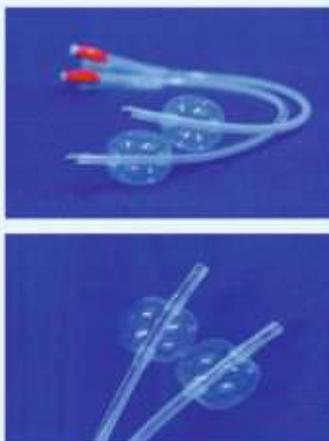
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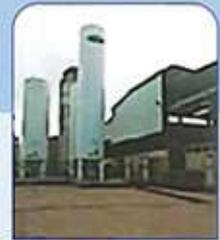
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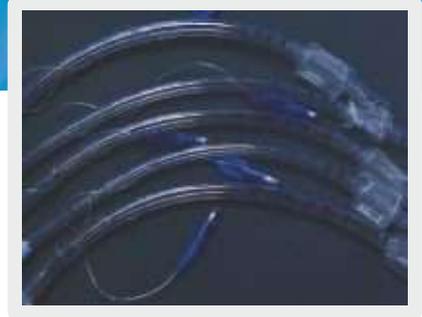
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